DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 801, and 1100

[Docket No. FDA–2015–N–2002]

RIN 0910–AH19

Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding ''Intended Uses''

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing regulations to describe the circumstances in which a product made or derived from tobacco that is intended for human consumption will be subject to regulation as a drug, device, or a combination product under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This action is intended to provide direction to regulated industry and to help avoid consumer confusion.

DATES: Submit either electronic or written comments on this proposed rule by November 24, 2015. See section IV.B of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA–2015–N–2002 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Request for Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Bryant Godfrey or Darin Achilles, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20993–0002, 877–287–1373, *CTPRegulations@fda.hhs.gov.*

Executive Summary

Purpose of the Proposed Rule

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) amends the FD&C Act and provides FDA with the authority to regulate tobacco products. Section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), as amended by the Tobacco Control Act, defines the term ''tobacco product'' as any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). Excluded from the definition of a tobacco product is any article that is a drug, device, or combination product. Any article that is a drug, device, or combination product will be regulated as such rather than as a tobacco product.

Because some ambiguity surrounds the circumstances under which a product that is made or derived from tobacco would be regulated as a drug, device, or combination product, and the circumstances under which it would be regulated as a tobacco product, FDA is initiating this rulemaking to provide clarity regarding our interpretation of the drug and device definitions in the FD&C Act with respect to products made or derived from tobacco. This rulemaking will provide assistance for entities intending to market products made or derived from tobacco. FDA expects the rule will also assist investigators planning to use products made or derived from tobacco for an investigational use in determining the investigational use requirements that apply to their proposed studies. The rulemaking will increase clarity regarding the types of claims and other evidence that make a product made or derived from tobacco subject to regulation as a drug, device or combination product, helping consumers distinguish products made or derived from tobacco that are intended for medical use from products marketed for other uses.

In addition, FDA is taking the opportunity to propose corresponding changes to existing regulations at §§ 201.128 and 801.4 (21 CFR 201.128 and 801.4), and to conform them to how the Agency currently applies these regulations to drugs and devices generally.

Summary of the Major Provisions of the Regulatory Action

Conceptually, the proposed rule follows the disease prong and the structure/function prong (with certain enumerated limitations) of the statutory definitions of ''drug'' and ''device'' (section 201(g) and (h) of the FD&C Act). Under the proposed rule, a product made or derived from tobacco and intended for human consumption would be regulated as a drug, device, or combination product in two circumstances: (1) If the product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or (2) if the product is intended to affect the structure or any function of the body in any way that is different from effects of nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000. The proposed rule also attempts to clarify remaining circumstances where a product would be or could be regulated as a tobacco product.

In addition, FDA is proposing to amend its existing intended use regulations for drugs and devices by inserting in §§ 201.128 and 801.4 a reference to the proposed rule to clarify the interplay between these regulations and this proposed rule, and to conform §§ 201.128 and 801.4 to reflect how the Agency currently applies them to drugs and devices.

Costs and Benefits

The proposed rule would generate some benefit by reducing the ambiguity in the development and marketing of products made or derived from tobacco. The proposed rule is not expected to impose significant additional costs on manufacturers who make products made or derived from tobacco, or on drug and device manufacturers generally.

SUPPLEMENTARY INFORMATION:

I. Background

A. Definition of ''Tobacco Product''

The Tobacco Control Act was enacted on June 22, 2009 (Pub. L. 111–31), amending the FD&C Act and providing FDA with the authority to regulate tobacco products. Section 101(a) of the Tobacco Control Act amends section 201 of the FD&C Act by adding paragraph (rr), which defines the term ''tobacco product.'' In general, a ''tobacco product'' is defined as any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). Section 201(rr)(2) of the FD&C Act excludes from the definition of a tobacco product any article that is defined as a drug under section 201(g)(1), a device under section 201(h), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C 353(g)). Section 201(rr)(3) of the FD&C Act explains that any article that is a drug, device, or combination product will be regulated under chapter V of the FD&C Act (the authorities for drugs and devices) rather than chapter IX (the authorities for tobacco products).[1]

B. Drug/Device/Combination Product Definitions

1. Medical Product Definitions

As noted in section I.A of this document, the definition of ''tobacco product'' excludes anything that is a ''drug,'' ''device,'' or ''combination product'' under the FD&C Act. The FD&C Act defines ''drug'' (in relevant part) as an article intended either: (1) For use in the diagnosis, cure, mitigation, treatment, or prevention of disease (referred to as the ''disease prong'' of the definition), or (2) to affect the structure or any function of the body (the ''structure/function prong'') (section 201(g)(1) of the FD&C Act). The FD&C Act defines a ''device'' (in relevant part) as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, intended either: (1) For use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or (2) to affect the structure or any function of the body, and which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent on being metabolized for the achievement of its primary intended purposes (section 201(h) of the FD&C Act).[2] Combination products are products that constitute a combination of a drug, device, or biological product (section 503(g) of the FD&C Act). Under the FD&C Act, the Secretary's determination of the primary mode of action of a combination product determines which Center at FDA will have primary jurisdiction over the product (section 503(g) of the FD&C Act).

FDA has previously interpreted the exclusion in the tobacco product definition to mean that if a product made or derived from tobacco is determined to have a drug or device ''intended use,'' it will be regulated as a medical product, not as a tobacco product. As discussed in greater detail in this document, this interpretation was qualified in *Sottera, Inc.* v. *Food & Drug Administration,* 627 F.3d 891 (D.C. Cir. 2010), in which the D.C. Circuit applied the holding of *Food & Drug Administration* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 156 (2000), to all tobacco products. Thus, the determination of whether a product is a medical product or a tobacco product will be based on the FD&C Act and associated regulations and will also take into account relevant legal precedent (further described in section I.C of this document).

2. How Intended Use Is Determined

In determining a product's intended use, the Agency may look to ''any . . . relevant source,'' including but not limited to the product's labeling, promotional claims, and advertising (see, *e.g., Action on Smoking and Health* v. *Harris,* 655 F.2d 236, 239 (D.C. Cir. 1980); *United States* v. *Storage Spaces Designated Nos. ''8'' and ''49,''* 777 F.2d 1363, 1366 (9th Cir. 1985), *Hanson* v. *United States,* 417 F. Supp. 30, 35 (D. Minn.), *aff'd,* 540 F.2d 947 (8th Cir. 1976)). For example, FDA may take into account any claim or statement made by or on behalf of a manufacturer that explicitly or implicitly promotes a product for a particular use (see, *e.g.,* § 201.128 (drugs), § 801.4 (devices)).

To establish a product's intended use, FDA is not bound by the manufacturer or distributor's subjective claims of intent, but rather can consider objective evidence, which may include a variety of direct and circumstantial evidence. Thus, FDA may also take into account any circumstances surrounding the distribution of the product or the context in which it is sold (*see id.; see also U.S.* v. *Travia,* 180 F.Supp.2d 115, 119 (D.D.C. 2001)). In the context of medical products, generally, circumstantial evidence often ensures that FDA is able to hold accountable firms that attempt to evade FDA medical product regulation by avoiding making express claims about their products. As FDA has previously stated, however, the Agency would not regard a firm as intending an unapproved new use for an approved or cleared medical product based solely on the firm's knowledge that such product was being prescribed or used by doctors for such use (Ref. 5).

Thus, when a product made or derived from tobacco is marketed or distributed for an intended use that falls within the drug/device definitions, it would be regulated as a medical product, subject to the limitations discussed further in this document. Courts have recognized that products made or derived from tobacco marketed with ''disease'' claims and certain ''structure/function'' claims are drugs (*see United States* v. *46 Cartons . . . Containing Fairfax Cigarettes,* 113 F.Supp. 336, 337, 338 (D. N.J. 1953) (cigarettes marketed for the prevention of respiratory diseases); *United States* v. *354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes,* 178 F.Supp. 847, 851 (D. N.J. 1959) (cigarettes marketed for weight reduction)).

C. History of 1996 Rulemaking and Relevant Litigation

Although the courts have recognized that tobacco-derived products can be regulated as medical products under the FD&C Act in certain circumstances, courts have also held that there are limitations on how the drug and device definitions can be applied to products made or derived from tobacco. This section provides a summary of FDA regulatory action and related litigation relevant to those limitations.

In 1996, FDA issued a regulation restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents (the 1996 rule) (61 FR 44396, August 28, 1996). This rule included FDA's determination that it had jurisdiction over cigarettes and smokeless tobacco under the FD&C Act. The basis for this determination was that cigarettes and smokeless tobacco were intended to affect the structure or function of the body, within the FD&C Act definitions of the terms ''drug'' and ''device,'' because nicotine has significant pharmacological effects. In

[1] Section 201(rr)(4) of the FD&C Act prohibits a tobacco product from being marketed in combination with any other article or product regulated under the FD&C Act. This rulemaking does not address section 201(rr)(4).

[2] In this proposed rule, the cited language may be referred to as the ''drug/device definitions.''

addition, FDA found that cigarettes and smokeless tobacco were combination products consisting of the drug nicotine and device components intended to deliver nicotine to the body. In the 1996 rule, FDA concluded that cigarettes and smokeless tobacco should be regulated under the device authorities of the FD&C Act. The 1996 rule was challenged in court by a group of tobacco manufacturers, retailers, and advertisers on the grounds that FDA lacked jurisdiction to regulate tobacco products ''as customarily marketed;'' that the regulations exceeded FDA's authority to regulate devices; and that the advertising restrictions violated the First Amendment.

The Supreme Court struck down the 1996 rule in *Food & Drug Administration* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 156 (2000), holding that FDA lacked jurisdiction over tobacco products ''as customarily marketed.'' The Court found that Congress intended to exclude tobacco products from FDA's jurisdiction. In *Brown & Williamson,* the Court determined that tobacco products could not be made safe and effective for their intended uses, and therefore, FDA would have to remove them from the market, but that Congress had foreclosed such action (529 U.S. at 135–139). The Court also observed that Congress, in enacting statutes to regulate the labeling and advertising of conventional tobacco products, such as cigarettes and smokeless tobacco, had ''effectively ratified FDA's long-held position'' that the Agency lacked jurisdiction to regulate tobacco products ''absent claims of therapeutic benefit by the manufacturer'' (529 U.S. at 144).

In 2008 and early 2009, FDA detained multiple shipments of electronic cigarettes from overseas manufacturers and denied them entry into the United States on the ground that electronic cigarettes were unapproved drug-device combination products under the FD&C Act. In April 2009, plaintiffs sought a preliminary injunction to enjoin FDA from regulating electronic cigarettes as drug-device combination products and from denying entry of those products into the United States.[3] Between the filing of the lawsuit and a decision on the motion for a preliminary injunction, Congress passed the Tobacco Control Act and the President signed it into law. The District Court subsequently granted a preliminary injunction, relying on *Brown & Williamson* and the recently enacted Tobacco Control Act (*Smoking Everywhere, Inc.* v. *FDA,* 680 F. Supp. 2d 62 (D.D.C. 2010)). FDA appealed the decision and the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) affirmed in *Sottera, Inc.* v. *Food & Drug Administration,* 627 F.3d 891 (D.C. Cir. 2010).[4] The D.C. Circuit determined that the decision in *Brown & Williamson* was not limited to tobacco products that were the subject of the specific federal legislation discussed in that case. The D.C. Circuit found that under the Tobacco Control Act, all products made or derived from tobacco and intended for human consumption that are ''marketed for therapeutic purposes'' are subject to FDA's drug and/or device provisions, whereas ''customarily marketed tobacco products'' are subject to regulation as ''tobacco products'' (*Sottera,* 627 F.3d at 898–899; *see also Brown & Williamson,* 529 U.S. at 144–156).

The Court in *Brown & Williamson* frequently referred to ''tobacco products as customarily marketed,'' but never defined that phrase. The Court contrasted that phrase with ''claims of therapeutic benefit'' (*see, e.g.,* 529 U.S. at 127, 158), which it also did not define. Neither of these terms is used in the FD&C Act. In *Sottera,* the D.C. Circuit relied on *Brown & Williamson* and repeated these phrases in describing contrasting types of products. The court in *Sottera* specifically equated ''therapeutic uses'' with the disease prong of the drug/device definitions in the FD&C Act and said that customarily marketed tobacco products were sold without therapeutic claims (627 F.3d at 894) and should be regulated as tobacco products under the FD&C Act, as amended by the Tobacco Control Act. But neither court provided specific guidance about what might constitute claims of therapeutic benefit, nor did they explain the relationship between ''tobacco products as customarily marketed'' and the structure/function prong of the drug/device definitions of the FD&C Act. In addition, no court has addressed whether certain structure/function claims for products made or derived from tobacco that generally were not made for ''tobacco products as customarily marketed'' should be treated as drug or device claims.[5]

II. Purpose of Rulemaking

Because some ambiguity surrounds the circumstances under which a product that is made or derived from tobacco would be regulated as a drug, device, or combination product, and the circumstances under which it would be regulated as a tobacco product, we are initiating this rulemaking to provide clarity regarding our interpretation of the drug/device definitions in the FD&C Act with respect to products made or derived from tobacco. We believe that this rulemaking will provide assistance for entities intending to market products made or derived from tobacco and for entities that plan to study these products. For example, the rule is expected to help sponsors determine which FDA Center should be consulted as they develop their products and make appropriate premarket submissions to bring new products to market. FDA expects the rule will also assist investigators planning to use products made or derived from tobacco for an investigational use in determining the investigational use requirements that apply to their proposed studies. In addition, we believe it is important to avoid consumer confusion about which products are intended for medical uses versus recreational or other uses. The rulemaking will increase clarity regarding the types of claims and other evidence that make a product made or derived from tobacco subject to regulation as a drug or device, which we expect will help consumers distinguish products made or derived from tobacco that are intended for medical use from products marketed for other uses. Finally, the rulemaking will provide clarity for drug and device manufacturers generally regarding FDA's interpretation and application of its existing intended use regulations.

In both the *Brown & Williamson* and *Sottera* decisions, the courts set forth (but did not define) two poles—''tobacco products as customarily marketed'' and ''claims of therapeutic benefit''—and found that the ''customarily marketed'' pole was not within FDA's drug/device jurisdiction, but that the ''therapeutic benefit'' pole was within FDA's drug/device jurisdiction. As noted in section I.C of this document, the terminology used by the courts in establishing these two poles is not the terminology used by the FD&C Act in defining drugs and devices. Instead, the FD&C Act's drug and device definitions reference, in

[3] The original district court case was filed by Smoking Everywhere, Inc., and the case was joined by Sottera, Inc., which does business as NJOY.

[4] On January 24, 2011, the D.C. Circuit denied the government's petitions for rehearing and rehearing en banc (by the full court). *See Sottera* v. *FDA,* No. 10–5032 (D.C. Cir. Jan. 24 2011) (per curiam).

[5] In *Sottera,* there are a few instances where the court's opinion could be read to suggest that all products made or derived from tobacco that do not have therapeutic claims are tobacco products as customarily marketed (627 F.3d at 895, 898–899). However, to the extent that the issue of drug/device jurisdiction over structure/function intended uses that are not related to the commonly understood effects of nicotine was not before the court, this reading is dicta in any case.

relevant part, diagnosis, cure, mitigation, treatment, or prevention of disease (disease prong) and effects on the structure or any function of the body (structure/function prong). In addition, while certain products and claims may fall clearly at one pole or the other, a spectrum of products and claims may fall somewhere between the two poles. In the sections that follow, we describe our interpretation of the jurisdictional lines established by the FD&C Act's drug, device, and tobacco product definitions as informed by the decisions in *Brown & Williamson* and *Sottera.*

A. Claims About Products Made or Derived From Tobacco That Fall Within the Disease Prong

1. Disease Prong Claims

As discussed in section I.B, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease are drugs, devices, or combination products under the FD&C Act. Products made or derived from tobacco have historically been regulated as medical products when they are marketed for intended uses that fall within the disease prong. For example, FDA has approved a number of drug products made or derived from tobacco as nicotine replacement therapies with indications to reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking. Accordingly, FDA has long considered claims related to smoking cessation in the context of curing or treating nicotine addiction and its symptoms to be within FDA's ''disease prong'' jurisdiction.

FDA has also taken enforcement action against products made or derived from tobacco that were marketed with claims of therapeutic benefit but that did not have approved new drug applications. For example, FDA seized cigarettes on the grounds that they were misbranded drugs when the manufacturer represented that the cigarettes were effective in preventing respiratory diseases, common cold, influenza, pneumonia, and various other ailments. (*United States* v. *46 Cartons . . . Containing Fairfax Cigarettes,* 113 F.Supp. 336, 337, 338 (D. N.J. 1953)).

The ''therapeutic benefit'' language used by the *Brown & Williamson* and *Sottera* courts has a logical relationship to the disease prong of the drug/device definition, in that ''therapeutic'' can be defined as ''relating to the treatment of disease or disorders by remedial agents or methods or to providing or assisting in a cure.'' [6] As part of this rulemaking, FDA is clarifying the categories of claims relevant to products made or derived from tobacco that FDA considers to fall within the disease prong in light of the *Sottera* and *Brown & Williamson* decisions. As discussed previously, claims related to smoking cessation have long been recognized as claims conferring drug or device jurisdiction. Smoking cessation claims have also long been associated with curing or treating nicotine addiction and its symptoms. For example, the approved labeling for nicotine replacement therapies includes the following statements: ''Purpose: Stop smoking aid; Use: Reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking.'' [7] Against this backdrop, smoking cessation claims on any product generally create a strong suggestion of therapeutic benefit to the user that generally will be difficult to overcome absent clear context indicating that the product is not intended for use to cure or treat nicotine addiction or its symptoms, or for another therapeutic purpose.

Given the availability of FDA-approved drugs for smoking cessation, FDA believes that consumers are particularly susceptible to confusion where products made or derived from tobacco that otherwise appear to be products intended for recreational use make claims related to quitting smoking. Therefore, FDA considers claims related to smoking cessation to require careful scrutiny. Where products making claims related to quitting smoking also attempt to disclaim that use in some way, FDA intends to view such disclaimers skeptically because of the likelihood of consumer confusion. In most cases, FDA does not believe that disclaimers will sufficiently mitigate consumer confusion related to the intended therapeutic use of the product.

FDA proposes to treat several other categories of claims for products made or derived from tobacco as falling within the disease prong of the drug/device definition. These categories of claims are discussed further in section IV (Description of Proposed Regulation). We note that sections 911(c) and 918 of the FD&C Act (21 U.S.C. 387k(c) and 387r), as amended by the Tobacco Control Act, contemplate that products intended for the treatment of tobacco dependence and for relapse prevention, among other things, may be subject to FDA's drug/device jurisdiction.

2. Distinction Between Disease Prong Claims and Modified Risk Claims

Through this rulemaking, FDA is also clarifying the relationship between FDA's regulation of a certain category of tobacco products—modified risk tobacco products (MRTPs)—and FDA's regulation of medical products that are intended to mitigate disease. MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products (section 911(b)(1) of the FD&C Act). The phrase ''sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products'' refers to a tobacco product:

1. That represents in its label, labeling, or advertising, either implicitly or explicitly, that:

- The tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;
- the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or
- the tobacco product or its smoke does not contain or is free of a substance;

2. That uses the descriptors ''light,'' ''mild,'' ''low,'' or similar descriptors in its label, labeling, or advertising; [8] or

3. For which the tobacco product manufacturer has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after June 22, 2009, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful

[6] See, *e.g.,* Merriam-Webster Online Dictionary, available at *http://www.merriam-webster.com/dictionary/therapeutic.*

[7] See, *e.g.,* approved labeling for Nicoderm CQ, Nicorette, Habitrol.

[8] Although cigarettes had been marketed with such descriptors before the Tobacco Control Act was enacted, as of June 22, 2010, manufacturers were prohibited from manufacturing for sale or distribution any tobacco products for which the label, labeling, or advertising contains the descriptors ''light,'' ''low,'' or ''mild,'' or any similar descriptor, without an FDA order in effect under section 911(g) of the FD&C Act (section 911(b)(3) of the FD&C Act). Furthermore, as of July 22, 2010, manufacturers, including importers of finished tobacco products, were prohibited from introducing into the domestic commerce of the United States any tobacco product for which the label, labeling, or advertising contains the descriptors ''light,'' ''low,'' or ''mild,'' or any similar descriptor, irrespective of the date of manufacture, without an FDA order in effect under section 911(g) of the FD&C Act (id).

than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

See section 911(b)(2) of the FD&C Act.[9]

Because MRTPs have the potential to be marketed as less harmful than other tobacco products, including as presenting a lower risk of tobacco-related disease than another tobacco product, FDA recognizes that there might be questions about how these products relate to FDA's medical product jurisdiction over products made or derived from tobacco that are intended for use in disease mitigation. MRTPs may have the ultimate effect of lowering disease risk for users who would otherwise use another, more harmful tobacco product. However, an important distinction between MRTPs and medical products is that, while medical products approved for disease mitigation act affirmatively to combat a disease or health condition, MRTPs present *relatively* less risk of disease (*e.g.,* by presenting reduced exposure to harmful constituents relative to another tobacco product), but do not affirmatively act to mitigate or otherwise treat disease. In addition, while medical products approved for disease mitigation are determined to be both safe and effective for their approved use, MRTPs are reviewed based, in part, on a ''benefit the health of the population as a whole'' standard, and like other tobacco products, still expose users to inherent (if reduced) harms.

For purposes of illustration, claims of modified risk might include claims like ''contains less nicotine than [tobacco product X]'', ''using [MRTP] reduces your risk of lung cancer compared to using [tobacco product X]'', and ''lower level of nitrosamines than other smokeless tobacco products.'' In contrast, a claim that a product ''inhibits the progression of disease in adult patients with chronic obstructive pulmonary disease (COPD)'' is not an appropriate modified risk claim, but would be appropriate for a medical product approved for such an indication.

[9] No smokeless tobacco product shall be considered to be sold or distributed for use to reduce harm or the risk of tobacco-related disease solely because its label, labeling, or advertising uses the following phrases: ''smokeless tobacco,'' ''smokeless tobacco product,'' ''not consumed by smoking,'' ''does not produce smoke,'' ''smokefree,'' ''smoke-free,'' ''without smoke,'' ''no smoke,'' or ''not smoke'' (section 911(b)(2)(C) of the FD&C Act).

B. Claims About Products Made or Derived From Tobacco That Fall Within the Structure/Function Prong

As discussed in sections I.B and I.C of this document, the drug/device definitions in the FD&C Act include articles ''intended to affect the structure or any function of the body,'' and FDA's assertion of jurisdiction over cigarettes and smokeless tobacco in 1996 was predicated on the pharmacological effects of nicotine on the structure or function of the body. In addition, as explained previously, the Court in *Brown & Williamson* rejected that assertion of jurisdiction, finding that Congress did not intend for FDA to have jurisdiction over cigarettes ''as customarily marketed.''

Based on the *Brown & Williamson* holding and the *Sottera* court's application of that holding to all tobacco products, FDA believes that the appropriate inquiry in determining whether a particular product made or derived from tobacco is ''customarily marketed''—and therefore outside of FDA's drug/device jurisdiction—is to determine whether any claims related to structure/function relate to effects of nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to the date of the Supreme Court's decision in *Brown & Williamson* (March 21, 2000).

For example, claims related to satisfaction, pleasure, enjoyment, and refreshment have been recognized as euphemisms for the delivery of a pharmacologically active dose of nicotine. While these claims relate to effects on the structure or function of the body, FDA does not consider these tobacco satisfaction and enjoyment claims to fall within its drug and device regulatory authority. Similarly, FDA does not consider claims suggesting that a tobacco product provides an alternative way of obtaining the effects of nicotine, or that a tobacco product will provide the same effects as another tobacco product—such as ''satisfying smoking alternative,'' ''provides all the pleasure of smoking,'' ''get your nicotine fix,'' or ''provides smokers the same delight, physical and emotional feelings''—to fall within its drug and device authority; however, we invite comment on this.

The *Brown & Williamson* and *Sottera* decisions do not reach the issue of intended uses that fall outside the disease prong of the drug/device definition *and* that are outside the area of ''customarily marketed'' tobacco product claims. FDA believes certain structure/function claims for products made or derived from tobacco continue to fall within our drug/device regulatory authority. FDA believes these structure/function claims fall into two main categories: (1) Claims that are unrelated to the pharmacological effects of nicotine, and (2) claims that were not commonly and legally made for cigarettes and smokeless tobacco products (*i.e.,* the products addressed in the 1996 rule) prior to the Supreme Court's decision in *Brown & Williamson.* Thus, to the extent manufacturers intend products made or derived from tobacco to be used to affect the structure or function of the body in some manner that is not related to the effects of nicotine commonly and legally claimed prior to March 21, 2000, FDA would consider these intended uses to remain within its drug/device jurisdiction under the proposed rule. For example, if a product made or derived from tobacco is marketed with structure/function claims such as ''maintain healthy lung function,'' ''relieve tension,'' ''restore mental alertness,'' ''maintain memory,'' ''support the immune system,'' or ''promote weight loss,'' FDA would consider such intended uses to fall within its drug/device jurisdiction.

FDA believes that it is important to distinguish structure/function intended uses that were not commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to the decision in *Brown & Williamson.* Structure/function intended uses are a long-standing and important aspect of FDA's medical product jurisdiction, grounded in the statutory definitions of ''drug'' and ''device'' in the FD&C Act. We recognize that products made or derived from tobacco are unique because of the regulatory regime for tobacco products under the FD&C Act, and that some products made or derived from tobacco making certain structure/function claims are now outside our drug/device jurisdiction. However, we believe it is important from a public health perspective, and consistent with the FD&C Act and case law, to preserve our traditional medical product authority over products made or derived from tobacco whose intended use includes effects on the structure or function of the body that are distinct from the pharmacological effects of nicotine that were commonly and legally claimed before March 21, 2000.

FDA believes this proposed rule will provide clarity to manufacturers about how products made or derived from tobacco will be regulated if they are marketed or distributed for certain intended uses. This clarification will

allow regulated industry to plan accordingly during the product development and postmarketing phases and will help researchers understand the applicable regulatory requirements associated with the investigational use of products made or derived from tobacco.

In addition, we believe this proposed rule will help to avoid consumer confusion about which products made or derived from tobacco are intended for a medical use (*i.e.,* as a drug/device) versus for a recreational use. Specifically, FDA wishes to avoid situations where products intended to be sold as tobacco products are marketed with the same claims as products sold as drugs or devices. If tobacco products are marketed in ways that make them hard to distinguish from certain medical products, consumers may use tobacco products, which are inherently dangerous, in place of FDA-approved medical products that have been determined to be safe and effective for their intended use.

C. Proposed Changes to Existing ''Intended Use'' Regulations

FDA is also proposing changes to §§ 201.128 and 801.4. First, the proposed rule would insert a reference to § 1100.5 to clarify the interplay between these regulations and the proposed rule. Second, as discussed previously, the Agency does not regard a firm as intending an unapproved new use for an approved or cleared medical product based solely on that firm's knowledge that such product was being prescribed or used by doctors for such use (see Ref. 5). Accordingly, FDA is taking this opportunity to amend §§ 201.128 and 801.4 to better reflect FDA's interpretation and application of these regulations. These changes would not reflect a change in FDA's approach regarding evidence of intended use for drugs and devices. These clarifying changes to the intended use regulations would apply to drugs and devices generally, and not just to products made or derived from tobacco and intended for human consumption.

III. Legal Authority

Among the provisions of the FD&C Act that provide authority for this proposed rule are sections 201, 503(g), and 701(a) of the FD&C Act (21 U.S.C. 321, 353(g), 371(a)). Section 201 of the FD&C Act defines ''drug,'' ''device,'' and ''tobacco product'' (subsections (g)(1), (h), and (rr)(1)), and section 503(g) of the FD&C Act provides that combination products are those ''that constitute a combination of a drug, device, or biological product.'' Under section 701(a) of the FD&C Act, FDA has authority to issue regulations for the efficient enforcement of the FD&C Act.

FDA regulates the manufacture, sale, and distribution of drugs, devices, combination products, and tobacco products under the authority of the FD&C Act. Although the regulatory pathways for each product category differ, each product category is subject to similar types of regulatory requirements. For example, FDA's regulatory authority for drugs, devices, combination products, and tobacco products includes authority to review and authorize the marketing of new products as well as to oversee product labeling and advertising. Thus, whether a product meets the definition of a drug, device, or tobacco product under the FD&C Act and this proposed regulation, the manufacture, sale, and distribution of the product are subject to the applicable requirements of the FD&C Act.

IV. Description of Proposed Regulation

A. Exclusion From Tobacco Product Regulation (Proposed § 1100.5)

As described in section II of this document, the goal of this proposed rule, when finalized, is to provide clarity regarding the types of intended uses of products made or derived from tobacco that may fall within the drug/device definitions and therefore cause those products to be regulated as medical products under the FD&C Act. In describing these intended uses, the proposed rule aims to assist regulated entities in the research and development of products made or derived from tobacco by clarifying which regulatory framework (*i.e.,* the drug/device frameworks or the tobacco framework) will apply to particular products based on their intended use. The proposed rule is also intended to reduce consumer confusion regarding which products are intended for medical use (*i.e.,* as a drug, device, or combination product) and which may be marketed for recreational or other purposes. The proposed rule reflects the legal and regulatory considerations discussed in sections I and II of this document, including the *Brown & Williamson* and *Sottera* holdings. Finally, the proposed rule would amend the existing intended use regulations for drugs and devices by inserting in §§ 201.128 and 801.4 a reference to § 1100.5 to clarify the interplay among these regulations and this proposed rule.

The proposed codified language states the circumstances in which a product made or derived from tobacco would be excluded from the definition of ''tobacco product'' and be subject to regulation as a drug, device, or combination product. Under the proposed rule, this exclusion could apply in two circumstances: (1) If the product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or (2) if the product is intended to affect the structure or any function of the body, in any way that is different from effects of nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000.

Conceptually, the proposed codified language follows the disease prong and the structure/function prong (with certain limitations) of the drug and device definitions.

1. Disease Prong

Proposed § 1100.5(a) follows the disease prong. The proposed paragraph elaborates on the statutory language for the disease prong by describing several categories of intended uses that would cause a product made or derived from tobacco to be regulated as a medical product. The categories identified in proposed § 1100.5(a) are not intended to constitute an exhaustive list; nor are these categories necessarily mutually exclusive. In addition, these categories are intended to capture concepts, rather than to suggest that the use (or omission) of particular words is dispositive with respect to FDA's medical product jurisdiction. These categories are included as examples of types of intended uses that we believe are particularly relevant for products made or derived from tobacco and that fall within the disease prong.

2. Structure/Function Prong

Proposed § 1100.5(b) follows the structure/function prong, but with some changes to reflect the court decisions in *Brown & Williamson* and *Sottera.* Specifically, the language in proposed § 1100.5(b) beginning ''in any way that is different from . . . '' reflects the fact that, under *Brown & Williamson* and *Sottera,* certain structure/function claims about the effects of nicotine will not confer drug/device jurisdiction to the extent they reflect those made for ''customarily marketed'' tobacco products. This language also references ''the marketing of cigarettes and smokeless tobacco products'' because these were the product categories considered by the Supreme Court in *Brown & Williamson.* March 21, 2000, is the date of the Supreme Court's ruling in *Brown & Williamson.*

FDA believes that it is important to include a date limitation in proposed § 1100.5(b) to provide greater certainty about the universe of structure/function claims the Agency intends to consider when determining whether a product made or derived from tobacco is ''customarily marketed.'' This bright-line limitation also avoids creating a shifting standard that will cause confusion among consumers and regulated industry. FDA intends to look to the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000, to determine the types of structure/function claims that constitute customary tobacco product marketing. Examples of these types of claims include those related to satisfaction, pleasure, enjoyment, and refreshment (*e.g.,* ''[Brand X] refreshes while you smoke''). Cigarettes and smokeless tobacco products provide a reasonable proxy for determining how nicotine-related structure/function claims were conveyed in tobacco product marketing generally. The proposed codified language, however, applies to all products made or derived from tobacco, not just cigarettes and smokeless tobacco. The proposed codified language also applies regardless of whether a product made or derived from tobacco has been deemed to be subject to the tobacco product authorities in the FD&C Act.

3. Intended Use

As noted in section I.B.2 of this document, intended use may be determined from any relevant source and is not based solely on claims made in a product's labeling or advertising materials. For purposes of illustration, however, claims such as ''treatment of tobacco dependence,'' ''wean yourself off of nicotine,'' ''for people who wish to quit smoking,'' ''stop smoking aid,'' ''prevent relapse,'' or ''stay quit'' generally would fall within the intended uses described in proposed § 1100.5(a).[10]

Claims such as ''to reduce withdrawal symptoms,'' ''helps reduce symptoms including things like [list of withdrawal symptoms]'' and ''relieve withdrawal symptoms while you are on the plane'' would be associated with an intended use for relief of nicotine withdrawal symptoms, and would also fall within the intended uses described in proposed § 1100.5(a). Withdrawal symptoms that are medically recognized as relevant to nicotine addiction may be determined by reference to standard classification and diagnostic tools such as the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM–5) and the tenth revision of the International Statistical Classification of Diseases and Related Health Problems (ICD–10).

Certain structure/function claims that were not commonly and legally made in the marketing of cigarettes and smokeless tobacco products before March 21, 2000, such as ''promotes weight loss,'' would fall within the intended uses described in proposed § 1100.5(b).

In contrast to the examples of medical product intended use claims given in the previous paragraphs, certain other claims made about products made or derived from tobacco would not on their own create an intended use that falls within the proposed codified language.[11] For example, claims such as ''smoke free, spit free tobacco pleasure'' or ''full taste and satisfaction'' may be associated with the marketing of tobacco products for refreshment, satisfaction, or enjoyment. Claims such as ''great tasting tobacco satisfaction when you can't smoke,'' ''satisfying tobacco alternative,'' or ''provides the look, feel, and experience of a cigarette'' may be associated with the marketing of tobacco products as smoking substitutes. And claims such as ''healthier alternative to smoking,'' ''contains less nicotine than [another product],'' or ''reduces your risk of lung cancer compared to cigarettes'' might be associated with MRTPs, as discussed in section II.A of this document.

In addition, as discussed previously, a manufacturer's knowledge that an approved or cleared medical product is being used for an unapproved use, would not by itself establish a medical product intended use. To clarify FDA's policy on this point, as well as the interplay among §§ 201.128, 801.4, and proposed 1100.5, FDA is proposing revisions to §§ 201.128 and 801.4.

For products made or derived from tobacco that are intended for investigational use, FDA will consider whether the product is being used in a clinical investigation for an intended use that brings it within the proposed codified language. If it is, the product would meet the definition of ''investigational new drug'' in § 312.3 (21 CFR 312.3), and the clinical investigation would be subject to the applicable requirements in 21 CFR part 312.[12] Products made or derived from tobacco that are intended for investigational use but that do not meet the definition of ''investigational new drug'' in § 312.3 may be subject to regulation as investigational tobacco products under section 910(g) of the FD&C Act (21 U.S.C. 397j(g)). FDA encourages sponsors and researchers with questions about whether a product being used in a clinical investigation would be subject to regulation as an ''investigational new drug'' or as an ''investigational tobacco product'' to contact either the Center for Drug Evaluation and Research or the Center for Tobacco Products.

B. Proposed Effective Date

The Agency proposes that any final rule based on this proposal will become effective 30 days after the date of publication of the final rule in the **Federal Register**. During the pendency of this rulemaking, manufacturers will continue to be under an obligation to comply with all applicable provisions of the FD&C Act and applicable regulations.

V. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. National Environmental Policy Act

FDA has determined under 21 CFR 25.30(h) and (k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,

[10] These and other specific claims mentioned in this document are provided solely as examples. Other claims not mentioned in this document could also reflect an intended use described in the proposed codified language. In addition, as discussed elsewhere in this document, FDA intends to consider the full context of claims for products made or derived from tobacco in making jurisdictional determinations.

[11] As previously, the specific claims mentioned in this paragraph are provided solely as examples. Other claims not mentioned here could fall outside the intended uses described in proposed § 1100.5.

[12] Note that studies performed to meet statutory requirements in chapter IX of the FD&C Act relating to the impact of tobacco products on cessation behavior are not required to be designed as clinical investigations subject to the investigational new drug application (IND) requirements in 21 CFR part 312. Whether a study is considered a clinical investigation of an ''investigational new drug'' would depend on the study's design and specific objectives.

neither an environmental assessment nor an environmental impact statement is required.

VII. Analysis of Impacts

A. Introduction and Summary

1. Introduction

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. By clarifying when products made or derived from tobacco will be subject to regulation as medical products, the ambiguity that currently exists in the regulatory environment will be reduced. We cannot predict how many companies will revise labeling, advertising, or other marketing materials for their products following issuance of this rule. We note, however, that this regulation is intended to provide clarity regarding existing jurisdictional lines for products made or derived from tobacco and for drug and device manufacturers regarding FDA's interpretation and application of its existing intended use regulations; as such, any need to revise labeling, advertising, or other marketing materials or submit applications should have predated the regulation. Therefore, the Agency proposes to certify that the proposed rule will not have a significant economic burden on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million (Ref. 1), using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

2. Summary

The proposed rule would reduce the ambiguity in the market for products made or derived from tobacco and clarify FDA's interpretation and application of its existing intended use regulations. The rule clarifies the types of claims and other evidence that would result in these products being regulated as medical products rather than tobacco products. The reduction in ambiguity should increase appropriate market participation and thus increase welfare in the market, including greater clarity and less confusion for producers and consumers. While these clarifications would impact future marketing strategies, it is not expected to result in significant changes to current marketing costs.

B. Preliminary Regulatory Impact Analysis

1. Benefits

Adopting the proposed rule would clarify the regulatory status of products made or derived from tobacco and how FDA interprets and applies its existing intended use regulations. This is expected to reduce the ambiguity associated with submitting a new product for approval or marketing authorization, or with initiating research of a new product. It is expected that industries are ambiguity averse.

Ambiguity aversion is preference of certainty over uncertainty (Ref. 2). It is assumed that industries developing and manufacturing products made or derived from tobacco prefer a regulatory environment with greater certainty than one with greater ambiguity. Previous research has shown that reduction in the uncertainty of financial markets increases participation by both traders and investors (Refs. 3 and 4). The proposed rule is expected to reduce ambiguity, and this reduction in ambiguity will encourage investment and innovation.

2. Costs

The proposed rule is not expected to impose significant additional costs on drugs, devices, or tobacco products. FDA's regulatory authority for drugs, devices, and tobacco products includes authority to review and authorize marketing of new products, as well as to oversee product labeling and advertising. Thus, whether a product meets the definition of a drug, device, or tobacco product under the FD&C Act and this proposed regulation, its manufacture, sale, and distribution is subject to the applicable requirements of the FD&C Act. Companies may revise marketing practices to conform to the rulemaking and to ensure they are incurring the appropriate costs for their product type. We do not have evidence that this will affect many currently marketed products and as such is unlikely to impose significant new costs.

The proposed rule does not extend FDA's authority to additional products and it does not impose any additional labeling requirements on currently regulated products. The proposed rule does not change the way FDA regulates medical products or tobacco products; it clarifies the applicable regulatory framework for products made or derived from tobacco and FDA's interpretation and application of its existing intended use regulations. This will reduce ambiguity for firms potentially seeking marketing authorization for a product as a drug, device, or tobacco product, will assist those seeking to study products made or derived from tobacco, and will help consumers differentiate between products that are intended for medical use and products marketed for other uses.

3. Summary and Discussion

The proposed rule is expected to reduce regulatory ambiguity in the research, development and marketing of drugs, devices, and tobacco products, as well as consumer confusion in the marketplace. The reduction in ambiguity will encourage investment and innovation. The proposed rule may affect marketing strategies, but is only clarifying when products made or derived from tobacco will be regulated as drugs or devices and FDA's interpretation and application of its existing intended use regulations. Accordingly, any costs to revise marketing strategies predated the rule, and as such the rule itself is not expected to impose significant costs.

C. Small Entities Effects

The Regulatory Flexibility Act requires Agencies to prepare a regulatory flexibility analysis if a proposed rule would have a significant effect on a substantial number of small businesses, non-profit organizations, local jurisdictions, or other entities. The proposed rule would reduce ambiguity in the regulatory environment for products made or derived from tobacco. We do not expect this clarification to significantly increase costs associated

with marketing products made or derived from tobacco, and thus certify that the proposed rule would not significantly affect a substantial number of small businesses, non-profit organizations, local jurisdictions, or other entities.

VIII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Request for Comments

A. General Information About Submitting Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document.

B. Public Availability of Comments

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.* As a matter of Agency practice, FDA generally does not post comments submitted by individuals in their individual capacity on *http://www.regulations.gov.* This is determined by information indicating that the submission is written by an individual, for example, the comment is identified with the category ''Individual Consumer'' under the field titled ''Category (Required),'' on the ''Your Information'' page on *http://www.regulations.gov.* For this proposed rule, however, FDA will not be following this general practice. Instead, FDA will post on *http://www.regulations.gov* comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

C. Information Identifying the Person Submitting the Comment

Please note that your name, contact information, and other information identifying you will be posted on *http://www.regulations.gov* if you include that information in the body of your comments. For electronic comments submitted to *http://www.regulations.gov,* FDA will post the body of your comment on *http://www.regulations.gov* along with your state/province and country (if provided), the name of your representative (if any), and the category identifying you (*e.g.,* individual, consumer, academic, industry). For written submissions submitted to the Division of Dockets Management, FDA will post the body of your comments on *http://www.regulations.gov,* but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

X. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address in this reference section, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. U.S. Department of Commerce, Bureau of Economic Analysis. *National Income and ProductAccounts, Table 1.1.9 Implicit Price Deflators for Gross Domestic Product,* December 23, 2014 (*http://www.bea.gov/national/Index.htm#gdp).*
2. Ellsberg, D. ''Risk, Ambiguity, and the Savage Axioms.'' *The Quarterly Journal of Economics* 75, no. 4: 643–669, November 1961.
3. Easley, D., and M. O'Hara. ''Ambiguity and Nonparticipation: The Role of Regulation.'' *Review of Financial Studies* 22, no. 5: 1817–1843, 2009.
4. Dimmock, S. G., R. Kouwenberg, O. S. Mitchell, et al. ''Ambiguity Aversion and Household Portfolio Choice: Empirical Evidence.'' *NBER Working Paper Series,* Working Paper 18743, January 2013.
5. Defendant's Memorandum of Points and Authorities In Support of Motion to Dismiss or Summary Judgment. *Allergan Inc.,* v. *United States of America, et. al.,* 1:09-cv-01879–JDB (D.D.C. Jan. 11, 2010).

List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 1100

Combination products, Devices, Drugs, Smoking, Tobacco.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I be amended as follows:

PART 201—LABELING

■ 1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

■ 2. Revise § 201.128 to read as follows:

§ 201.128 Meaning of ''intended uses''.

The words *intended uses* or words of similar import in §§ 201.5, 201.115, 201.117, 201.119, 201.120, 201.122, and 1100.5 of this chapter refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses.

PART 801—LABELING

■ 3. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

■ 4. Revise § 801.4 to read as follows:

§ 801.4 Meaning of intended uses.

The words *intended uses* or words of similar import in §§ 801.5, 801.119, 801.122, and 1100.5 of this chapter refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown, for example, by circumstances in which the article is, with the knowledge of such

persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the device, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses.

PART 1100—TOBACCO PRODUCTS SUBJECT TO FDA AUTHORITY

■ 5. The authority citation for 21 CFR part 1100 continues to read as follows:

Authority: 21 U.S.C. 387a(b), 387f(d); Secs. 901(b) and 906(d), Pub. L. 111–31; 21 CFR 16.1 and 1107.1; 21 CFR 1.1, 1.20, 14.55, 17.1, and 17.2. Section 1100.5 is issued under 21 U.S.C. 321, 353(g), and 371(a); 21 CFR 1.1.

■ 6. Part 1100, as proposed to be added on April 25, 2014 (79 FR 23142 at 23202), is amended by adding § 1100.5 to read as follows:

§ 1100.5 Exclusion from tobacco regulation.

If a product made or derived from tobacco that is intended for human consumption is intended for use for any of the purposes described in paragraph (a) or (b) of this section, the product is not a tobacco product as defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act and will be subject to regulation as a drug, device, or combination product.

(a) The product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, including use in smoking cessation, the cure or treatment of nicotine addiction, relapse prevention, relief of nicotine withdrawal symptoms, or prevention or mitigation of disease;

(b) The product is intended to affect the structure or any function of the body in any way that is different from effects related to nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000.

Dated: September 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24313 Filed 9–24–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1904

[Docket Number: OSHA–2015–0006]

RIN 1218–AC84

Clarification of Employer's Continuing Obligation To Make and Maintain an Accurate Record of Each Recordable Injury and Illness; Extension of Comment Period

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of proposed rule; extension of comment period.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is extending the deadline for submitting comments on the proposed rule: Clarification of Employer's Continuing Obligation To Make and Maintain an Accurate Record of Each Recordable Injury and Illness.

DATES: The comment due date for the proposed rule published in the **Federal Register** on July 29, 2015 (80 FR 45116) is extended. Comments must be submitted (postmarked, sent, or received) by October 28, 2015.

ADDRESSES: Submit comments and additional material using any of the following methods:

Electronically. You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the instructions on the Web site for making electronic submissions.

Facsimile. If your submission, including attachments, does not exceed ten pages, you may fax it to the OSHA Docket Office at (202) 693–1648. OSHA does not require hard copies of documents transmitted by facsimile. However, if you have supplemental attachments that are not delivered by facsimile, you must submit those attachments, by the applicable deadline, to the OSHA Docket Office, Technical Data Center, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–2625, Washington, DC 20210. Any such attachment must clearly identify the sender's name, the date of submission, the title of the rulemaking (Clarification of Employer's Continuing Obligation to Make and Maintain an Accurate Record of Each Recordable Injury and Illness), and the docket number (OSHA–2015–0006) so that the docket Office can add the attachment(s) to the appropriate facsimile submission.

Regular or express mail, hand delivery, or messenger (courier) service. You may submit comments to the OSHA Docket Office, Docket Number OSHA–2015–0006, Technical Data Center, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–2625, Washington, DC 20210; telephone: (202) 693–2350. (OSHA's TTY number is (877) 889–5627). Please contact the OSHA Docket Office for information about Department of Labor security procedures that could affect the delivery of materials by express mail, hand delivery, and messenger or courier service. Also note that security-related procedures may delay the Agency's receipt of comments submitted by regular mail. The Docket Office will accept deliveries by hand, express mail, or messenger and courier service during the Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m.

Instructions for submitting comments: All submissions must include the Agency's name (OSHA), the title of the rulemaking (Clarification of Employer's Continuing Obligation to Make and Maintain an Accurate Record of Each Recordable Injury and Illness), and the docket number (OSHA–2015–0006). OSHA will place comments and other material, including any personal information you provide, in the public docket without revision, and the comments and other materials will be available online at *http://www.regulations.gov.* Therefore, OSHA cautions you about submitting statements and information that you do not want made available to the public or that contain personal information (about yourself or others) such as Social Security numbers, birthdates, and medical data. For additional information on the rulemaking process, see the Background heading in the **SUPPLEMENTARY INFORMATION** part of this document.

Docket: To read or download comments or other material in the docket, go to Docket Number OSHA–20015–0006 at *http://www.regulations.gov* or to the OSHA Docket Office at the address provided previously. The electronic docket for this proposed rule, established at *http://www.regulations.gov,* lists all of the documents in the docket. However, some information (*e.g.,* copyrighted material) is not publicly available to read or download through that Web site. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.