Instructions:

* * * * *

6. * * *

(i) One or more tables, charts, or graphs depicting the portfolio holdings of the Registrant by reasonably identifiable categories (*e.g.,* type of security, industry sector, geographic region, credit quality, or maturity) showing the percentage of net asset value or total investments attributable to each. If the Registrant has sub-accounts, provide the information separately for each sub-account. The categories and the basis of presentation (*e.g.,* net asset value or total investments) should be selected, and the presentation should be formatted, in a manner reasonably designed to depict clearly the types of investments made by the Registrant, given its investment objectives. If the Registrant uses the credit ratings, as defined in Section 3(a)(60) [15 U.S.C. 78c(a)(60)] of the Exchange Act, assigned by a nationally recognized statistical rating organization ("NRSRO"), as defined in Section 3(a)(62) of the Exchange Act [15 U.S.C. 78c(a)(62)], to categorize the credit quality of portfolio holdings, it should use the credit ratings of only one NRSRO except in the case of portfolio holdings that are not rated by that NRSRO. If credit ratings of that NRSRO are not available for certain holdings, the Registrant must briefly discuss the methodology for determining credit quality for such holdings, including, if applicable, the use of credit ratings assigned by another NRSRO.

* * * * *

PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

10. Form N–MFP (referenced in § 274.201) is amended by:

a. Revising Item 33;

b. Removing Item 34;

c. Revising Item 37.b;

d. Removing Item 37.c;

e. Removing Items 38.b and 38.c;

f. Removing Items 39.c and 39.d;

g. Redesignating Items 35 through 46 as Items 34 through 45; and

h. In redesignated Item 38, replacing "Items 37 and 38" with "Items 36 and 37".

The revisions read as follows:

Note: The text of Form N–MFP does not, and this amendment will not, appear in the Code of Federal Regulations.

Form N–MFP

* * * * *

Item 33

Indicate whether the security is a First Tier Security, a Second Tier Security or no longer an Eligible Security.

* * * * *

Item 37

* * * * *

b. The period remaining until the principal amount of the security may be recovered through the Demand Feature.

Dated: March 3, 2011.

By the Commission.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–5184 Filed 3–8–11; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. FDA–1981–N–0012] (Formerly Docket No. 1981N–0022)

RIN 0910–AF45

Benzocaine; Weight Control Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed rule to reclassify benzocaine from its previously proposed monograph status (category I) for over-the-counter (OTC) weight control use to nonmonograph status. Although, in the **Federal Register** of February 26, 1982, an advanced notice of proposed rulemaking (ANPR) included the recommendation of an Advisory Panel, consisting of health care providers from outside FDA, recommended that benzocaine should be generally recognized as safe and effective (GRASE) for weight control, this document includes our first evaluation of benzocaine for this use. Based on our evaluation of the available data and information, we have tentatively concluded that the data are not sufficient to support the safety and effectiveness of benzocaine for this use. This proposed rule, if finalized, would require an approved new drug application (NDA) or abbreviated new drug application (ANDA) for the marketing of OTC weight control products containing benzocaine.

DATES: Submit written or electronic comments on the proposed rule by June 7, 2011. See section IX of this document for information on the proposed effective date of this proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA–1981–N–0012 (formerly Docket No. 1981N–0022 and RIN No. 0910–AF45 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:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM 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 Agency name and Docket No. FDA–1981–N–0012 (formerly Docket No. 1981N–0022) and RIN No. 0910–AF45 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided.

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: Michelle M. Jackson, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, MS 5411, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Purpose of This Document

In the **Federal Register** of February 26, 1982, we (FDA) published an ANPR to establish a monograph for OTC weight control drug products. The ANPR included the recommendations of an Advisory Review Panel on the OTC Miscellaneous Internal Drug Products (the Panel) that evaluated all OTC weight control drug products on the market at the time the OTC drug review began in 1972. The Panel consisted of

scientists and health care providers from outside FDA. The Panel concluded that "benzocaine is safe for oral use as an OTC anorectic in a dose of 3 to 15 milligrams (mg) in gum, lozenges, or candy" and that "benzocaine in the form of gum, lozenges, or candy is an effective OTC drug product for weight control" (47 FR 8466 at 8474). The Panel believed that benzocaine numbed the oral cavity (including the taste buds), thereby discouraging food consumption and decreasing caloric intake.

We reviewed the information and data available to the Panel as well as information and data that has been developed since the Panel met to help us determine whether benzocaine is GRASE when used in OTC weight control drug products. Under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), all "new drugs" are required to obtain approval under section 505 of the FD&C Act (21 U.S.C. 355) prior to marketing. Most drugs are "new drugs" under the FD&C Act; however, a drug is excluded from being a "new drug" (and therefore is not required to obtain approval under section 505) if it is "generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." (21 U.S.C. 321(p)(1)).[1]

As explained in this document, we tentatively conclude that the existing evidence is inadequate to establish that OTC weight control drug products containing benzocaine are GRASE. Accordingly, we are proposing to classify benzocaine as nonmonograph (i.e., not GRASE) for use in OTC weight control drug products. If this proposed rule becomes a final rule, OTC weight control drug products containing benzocaine will require an approved NDA or ANDA. Studies that may help demonstrate the safety and effectiveness of weight loss drug products are described in an FDA guidance entitled "Developing Products for Weight Management" (Ref. 1).

II. Rulemakings and Petitions for OTC Weight Control Drug Products

The Panel responsible for evaluating OTC weight control drug products recommended that benzocaine-containing drug products be deemed GRASE for use in OTC weight control drug products. The Panel's recommendations were published in the **Federal Register** as an ANPR for OTC weight control products in 1982 (47 FR 8466).

Following publication of the 1982 ANPR, Thompson Medical Co., a manufacturer of OTC weight control drug products, submitted two citizen petitions, one in 1990 and another in 1992, to support the effectiveness of benzocaine for use as an appetite suppressant (Refs. 2 and 3). The 1990 petition (Ref. 2) included a clinical study by Collipp (Refs. 4 and 5) and a summary of a clinical study by Piscano and Lichter (Ref. 6) as data supporting the effectiveness of benzocaine as an appetite suppressant. We responded to the manufacturer's 1990 petition (Ref. 7) reviewing the data submitted in the petition and explaining our finding that the data did not provide substantial evidence from adequate and well-controlled studies to support the effectiveness of benzocaine for weight control use.

The 1992 petition (Ref. 3) was submitted in response to our 1991 letter. The petition provided two unpublished statistical reevaluations of the Collipp study, arguing that this data supported finding benzocaine GRASE for use in OTC weight control drug products. We responded to the petition in 1993 (Ref. 8), stating that the reevaluations of the Collipp study did not substantiate the claim of effectiveness of benzocaine for use in weight control. The two reanalyses of the Collipp data include: (1) An analysis of covariance excluding subjects that failed to meet either the age or the degree of overweight inclusion criteria, and (2) a hierarchical regression model to determine the effect of benzocaine after attempting to control for any familial effects. Neither of these analyses adequately addressed the three main problems that were listed in the 1991 response: (1) Possible breaking of the blind; (2) imbalance in the sample for important variables (age by family status); and (3) lack of randomization within families, affecting the independence of observations. These problems potentially biased the data affecting the interpretability of the study results.

Subsequent to our letter, we received draft protocols for effectiveness studies (Ref. 9) from the same manufacturer, which were intended to generate support for a GRASE finding. We sent recommendations on the draft protocols in 1992 (Ref. 10), but have not yet received any study results.

III. Efficacy Evaluation

We are proposing that benzocaine be classified as nonmonograph at any concentration for use in OTC weight control drug products. This conclusion is based in part on our review of the effectiveness data that was submitted to the Panel (Refs. 11 through 17) and additional data submitted to us after publication of the 1982 ANPR, including the two petitions and draft protocols described previously (Refs. 2, 3, and 9). In our responses to the petitions, we explained in detail why we did not find the available data adequate to support a determination that benzocaine is generally recognized as effective (GRAE) for this use (Refs. 7, 8, and 10). In this document, we summarize the available data and limitations that prevent us from finding benzocaine GRAE for use in OTC weight control drug products. We have not received any additional data from any company or citizen since our 1992 response letter (Ref. 10) discussed previously; and we are not aware of any safety or effectiveness studies for benzocaine in OTC weight control drug products conducted since 1992.

In the following sections, we will first describe the studies reviewed by the Panel. After reviewing the data and findings from these studies, we will explain why the Agency has concluded that these studies do not support a finding that benzocaine is GRAE for use in OTC weight control drug products.

A. Non-Clinical Studies

1. Review of Studies

In the ANPR, we reported that the Panel considered a few nonclinical studies (Refs. 11, 12, and 13) on benzocaine for weight control. One of the factors involved in overeating and resulting obesity is the need to satisfy the sense of taste. Horowitze (Ref. 11) and Rosner (Ref. 12) showed that there appears to be a decreased ability to detect degrees of sweetness by taste perception after chewing gum containing benzocaine. Coons (Ref. 13) demonstrated the effects of a local anesthetic on hunger reduction in rats. The Panel considered this study to be an objective demonstration of the effectiveness of a local anesthetic on hunger reduction.

2. Analysis of Studies

We do not believe these studies support a GRAE determination because they do not demonstrate that decreased taste perception or decreased hunger results in weight loss. To find benzocaine GRAE based in part on these types of studies, we would also need data demonstrating what level of decrease in taste perception or hunger actually resulted in a "clinically

[1] Consistent with the principles explained previously, the OTC drug review regulations in 21 CFR 330.10 specify the considerations and evidence required to establish both safety and effectiveness.

significant benefit of the type claimed" (*i.e.,* weight loss) as required under § 330.10(a)(4)(ii) (21 CFR 330.10(a)(4)(ii)).

B. Clinical Studies

1. Review of Studies

The Panel also considered clinical studies that included weight loss as an endpoint. Gould (Refs. 14 and 15) assessed various case reports citing 1.5 to 2.0 pounds (lbs) per week weight loss using lozenges containing benzocaine and essential oils in conjunction with dietary restrictions. Plotz (Ref. 16) conducted an uncontrolled, non-randomized 10-week study of 50 overweight adults (12 to 102 lbs overweight). The subjects were instructed to chew one or two pieces of gum for 5 or 10 minutes followed by a glass of water, just before meals. If subjects became hungry between meals, they could chew gum every few hours. The study results showed weight loss (2 pounds per week) in 45 of 50 patients using the benzocaine gum in conjunction with dietary restrictions.

McClure and Brush (Ref. 17) conducted a placebo-controlled, randomized, double-blinded 21-week study of 308 overweight adults (255 females and 53 males). The subjects were divided into five paired treatment groups:

- Group 1: Dextroamphetamine sulfate (10 mg, daily)
- Group 2: OTC proprietary appetite suppressant (AYDS)
- Group 3: Dietary restriction (800 to 1,200 calories daily)
- Group 4: Glucose hard candy containing benzocaine, caffeine, and vitamins (benzocaine group)
- Group 5: Glucose candy only (control group)

Over the course of 4 weeks, 170 participants dropped out of the study (37 participants from the dextroamphetamine group, 43 participants from the AYDS group, 51 participants from the dietary restriction group, 9 participants from the benzocaine group, and 30 participants from the control group). The investigators reported an average weight loss during the first 4 weeks of 4.6 lbs for the glucose (control) group and 12.1 lbs for the benzocaine group. After 21 weeks, the control group lost a weekly average of 0.60 lbs as compared to 2.20 lbs for the benzocaine group.

In addition to these studies reviewed by the Panel, as described previously, we also reviewed clinical studies submitted by a manufacturer of OTC weight control drug products in two petitions. The studies provided in the petitions included weight loss as an endpoint. Reports purporting to be two studies by Collipp (one published and one unpublished) were submitted. These reports appear to be the same study (Refs. 4 and 5). The Collipp study was designed to be a 6-week, double-blind, placebo-controlled, randomized trial comparing benzocaine (5 mg) lozenges with placebo lozenges that were identical in appearance (Ref. 4). Male or female subjects who weighed 15 to 30 percent more than the ideal weight for their body frame as determined from Metropolitan Life Insurance Co. weight tables and were between 14 and 55 years of age were eligible for enrollment. Subjects were recruited from the same families. Subjects were instructed to follow a 1,250 calorie diet and to take 1 to 2 lozenges 10 minutes before meals, 1 lozenge instead of dessert, and 1 or 2 lozenges between meals. Subjects were also instructed to drink a glass of water, tea, coffee, or other non-caloric beverage with each lozenge ingestion. Body weight was measured at week 0 and biweekly for the next 6 weeks. Subjects were also asked to rate the average quality of between-meal appetite suppression as mild, moderate, or complete.

The study results showed that the mean body weight decreased from week 0 in both the active treatment and placebo groups. Subjects treated with benzocaine had a mean weight loss that was statistically significant ($p \leq: 0.001$) at all time points. The mean weight loss during the study was approximately twice as great for subjects treated with benzocaine (-3.5, -4.9, and -6.0 at 2, 4, and 6 weeks, respectively) compared to placebo (-2.1, -2.9, and -2.7 at 2, 4, and 6 weeks, respectively). The manufacturer also submitted a study by Piscano and Lichter (Ref. 6) which consisted of a 1-page summary describing an 8-week uncontrolled trial involving 26 children. The summary listed the baseline weight, final weight, and weight loss of each subject. The summary results showed that the subjects lost approximately 0.5 lbs/week. There was no protocol description and no statistical analysis.

2. Analysis of Studies

We found a lack of substantial evidence consisting of adequate and well-controlled studies, as required in § 330.10(a)(4)(ii), on which to base a determination of the effectiveness of benzocaine in OTC weight control drug products. In general, the clinical studies reviewed by the Panel (Refs. 14 through 17) are inadequately controlled, and study results were not clinically and statistically significant. For example, among other limitations, the Gould studies (Refs. 14 and 15) were not well-controlled, as these studies consisted of case reports. Similarly, the Plotz study (Ref. 16) was not well controlled, being both uncontrolled and non-randomized. Finally, as detailed in our 1993 response (Ref. 8), the McClure and Brusch study (Ref. 17) had significant methodological flaws including potential issues with subject recruitment, inconsistent follow up of subjects and inadequate assessment of baseline characteristics.

The materials submitted in the petition were also insufficient to establish the effectiveness of benzocaine in OTC weight control products. For example, the Pisano and Lichter (Ref. 6) study was not adequate and well-controlled as it consisted of case reports, did not include a protocol description and did not provide a statistical analysis. Similarly, the Collipp study and the reevaluations of the study submitted in the petitions do not provide detail regarding study design and outcomes sufficient to show benzocaine is GRASE for use in weight control. Specifically, the Collipp study had a significant number of limitations that prevent us from concluding that benzocaine is GRAE for weight control:

- Non-random selection of subjects
- Possible breaking of blinding
- Analysis did not account for a lack of independence among subjects within the same family, potentially affecting the study's findings

It is important to note that after providing the petitioning manufacturer with a response describing these limitations, we received a protocol for a further study from the manufacturer (Ref. 9). We provided feedback on the protocol in 1992 (Ref. 10), but we have not yet received the study results from the manufacturer. In order to establish effectiveness, additional data are still needed to show that benzocaine causes a clinically and statistically significant weight loss when compared with placebo. The industry is advised to consult a recently published FDA guidance on the development of products for weight management about the requirement of clinical data (Ref. 1).

IV. Safety Evaluation

We are not aware of adequate data to demonstrate that OTC weight control drug products containing benzocaine are generally recognized as safe (GRAS) as defined under § 330.10(a)(4)(ii). Under this regulatory provision, support for a GRAS showing "shall consist of adequate tests by methods reasonably applicable to show the drug is safe under the prescribed, recommended, or suggested conditions of use." We believe

that the safety of the Panel's proposed benzocaine dosing for OTC weight control use (multiple 3 to 15 mg doses for up to 3 months) has not been adequately established. Additional safety data is needed to establish dosage limitations or other aspects of the labeling. Our current recommendation as to what would constitute adequate testing for a weight control drug product is described in our guidance on weight control drug products (Ref. 1).

V. Analysis of Impacts

We have examined the impacts of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs 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). We believe that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because few products will likely be affected and those effects would probably be small, we do not believe that this proposed rule would have a significant economic impact 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 $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. We do not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

If this proposed rule is finalized, OTC marketing of weight control drug products containing benzocaine for this use will cease, unless a product is approved under an NDA or ANDA. In this proposed rule, we tentatively conclude that OTC weight control drug products containing benzocaine lack sufficient evidence to support a finding that such products are GRASE, and that finalization of the regulatory status of this ingredient will benefit consumers by removing from the marketplace products that have not been shown to be safe and effective. We do not expect this rule to have a significant effect on industry as a whole, as we have only been able to identify one company that manufactures a benzocaine-containing OTC weight control drug product.

We have few alternatives available to us when we determine there are no data available to demonstrate that an active ingredient is GRASE. Even without evidence of harm caused by the use of these products, they cannot remain on the market because there is no evidence that they are safe and effective. Accordingly, we have proposed a 30-day period within which companies may remove benzocaine-containing weight control drug products from the market. We believe the only alternative to this approach is a longer implementation period.[2] We could allow a longer implementation period so manufacturers would have time to submit additional effectiveness and safety data, but if we took this approach, consumers would be unnecessarily exposed to products that have not been shown to be effective or safe.

VI. Paperwork Reduction Act of 1995

This proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Environmental Impact

We have determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to "construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." The sole statutory provision giving preemptive effect to the proposed rule is section 751 of the act (21 U.S.C. 379r).

We believe that the preemptive effect of this proposed rule, if finalized, would be consistent with Executive Order 13132. Through the publication of this proposed rule, we are providing notice and an opportunity for State and local officials to comment on this rulemaking.

IX. Proposed Effective Date

Due to effectiveness concerns discussed in this document, any final rule based on this proposal would become effective 30 days after the date of its publication. Manufacturers are urged to comply voluntarily with this proposed rule and to cease OTC marketing at the earliest possible date.

X. References

The following references have been placed on display in the Division of Dockets Management (*see* **ADDRESSES**) under Docket No. FDA–1981–N–0012 (formerly 1981N–0022) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register.**)

1. FDA, "Draft Guidance for Industry—Developing Products for Weight Management," February 2007, *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071612.pdf*, accessed on August 27, 2010.
2. Comment No. CP12, Docket No. FDA–1981–N–0012 (formerly 1981N–0022), Division of Dockets Management System.
3. Comment No. CP15, Docket No. FDA–1981–N–0012 (formerly 1981N–0022), Division of Dockets Management System.
4. Collipp, P. J., "The Treatment of Exogenous Obesity by Medicated Benzocaine Candy: A Double-Blind Placebo-Controlled Study," in OTC Vol. 170010, Docket No. FDA–1981–N–0012 (formerly 1981N–0022), Division of Dockets Management.
5. Collipp, P. J., "The Treatment of Exogenous Obesity by Medicated Benzocaine Candy: A Double Blind Placebo Study," *Obesity/Bariatric Medicine,* 10:123–125, 1981.
6. Piscano, J. and H. Lichter, "A Matter of Taste," Fredrick Fell Publishers, Inc., New York, New York, pp. 42–64, 1979.
7. Comment No. LET82, Docket No. FDA–1981–N–0012 (formerly 1981N–0022), Division of Dockets Management System.
8. Comment No. LET87, Docket No. FDA–1981–N–0012 (formerly 1981N–0022), Division of Dockets Management System.
9. Comment No. PR9, Docket No. FDA–1981–N–0012 (formerly 1981N–0022), Division of Dockets Management System.
10. Comment No. LET84, Docket No. FDA–1981–N–0012 (formerly 1981N–0022), Division of Dockets Management System.

[2] *See* 5 U.S.C. 553(d).

11. Horowitz, S. and R. P. Scalici, "Results of Sensory Panel Tests on Slim-Mint Chewing Gum," in OTC Vol. 170010, Docket No. FDA–1981–N–0012 (formerly 1981N–0022), Division of Dockets Management.
12. Rosner, L., "To Determine the Effect of Chewing Slim-Mint Gum Upon Taste Perception, Particularly Toward Sweetness," in OTC Vol. 170010, Docket No. FDA–1981–N–0012 (formerly 1981N–0022), Division of Dockets Management.
13. Summary Minutes of the 11th meeting of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products held on May 9–10, 1976 in OTC Vol. 170010, Docket No. FDA–1981–N–0012 (formerly 1981N–0022), Division of Dockets Management.
14. Gould, W. L., "On the Use of a Medicament to Reduce the Appetite in the Treatment of Obesity and Other Conditions," *New York State Journal of Medicine,* 47:981–983, 1947.
15. Gould, W. L., "Obesity and Hypertension: The Importance of a Safe Compound to Control Appetite," *North Carolina Medical Journal,* 11:327–334, 1950.
16. Plotz, M., "Obesity," *Medical Times,* 86:860–863, 1958.
17. McClure, C. W. and C. A. Brusch, "Treatment of Oral Syndrome Obesity with Non traditional Appetite Control Plan," *Journal of the American Women's Medical Association,* 28:239–248, 1973.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

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 part 310 be amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

2. Section 310.545 is amended by adding paragraphs (a)(20)(i), (a)(20)(ii), and (a)(20)(iii); by revising paragraph (d) introductory text; and by adding paragraph (d)(40) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(20) * * *

(i) [Reserved]

(ii) [Reserved]

(iii) Approved as of [DATE 30 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**].

Benzocaine

* * * * *

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(40) of this section.

* * * * *

(40) [DATE 30 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], for products subject to paragraph (a)(20)(iii) of this section.

Dated: March 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5145 Filed 3–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 938

[PA–157–FOR; OSM 2010–0011]

Pennsylvania Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on removal of required amendment.

SUMMARY: We are announcing receipt of a request to remove a required amendment to the Pennsylvania regulatory program (the "Pennsylvania program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). In response to a required program amendment codified in the Federal regulations, Pennsylvania has submitted rationale that it believes supports its position that current program provisions are sufficient to render its program no less effective than the Federal requirements and, therefore, no amendment is necessary. The required amendment pertains to regulatory exemptions for coal extraction incidental to the extraction of other minerals.

This document gives the times and locations that the Pennsylvania program and this submittal are available for your inspection, the comment period during which you may submit written comments, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments until 4 p.m., local time April 8, 2011. If requested, we will hold a public hearing on April 4, 2011. We will accept requests to speak until 4 p.m., local time on March 24, 2011.

ADDRESSES: You may submit comments, identified by "PA–157–FOR; Docket ID: OSM–2010–0011" by either of the following two methods:

Federal eRulemaking Portal: http://www.regulations.gov. The proposed rule has been assigned Docket ID: OSM–2010–0011. If you would like to submit comments through the Federal eRulemaking Portal, go to *http://www.regulations.gov* and follow the instructions.

Mail/Hand Delivery/Courier: Mr. George Rieger, Chief, Pittsburgh Field Division, Office of Surface Mining Reclamation and Enforcement, Harrisburg Transportation Center, 415 Market St., Suite 304, Harrisburg, PA 17101.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, *see* the "Public Comment Procedures" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: In addition to obtaining copies of documents at *http://www.regulations.gov,* information may also be obtained at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Pittsburgh Field Division Office.

George Rieger, Chief, Pittsburgh Field Division, Office of Surface Mining Reclamation and Enforcement, Harrisburg Transportation Center, 415 Market St., Suite 304, Harrisburg, Pennsylvania 17101, *Telephone:* (717) 782–4036, *E-mail: grieger@osmre.gov.*

Thomas Callaghan, P.G., Director, Bureau of Mining and Reclamation, Pennsylvania Department of Environmental Protection, Rachel Carson State Office Building, P.O. Box 8461, Harrisburg, Pennsylvania 17105–8461, *Telephone:* (717) 787–5103, *E-mail: tcallaghan@state.pa.us.*

FOR FURTHER INFORMATION CONTACT: George Rieger, *Telephone:* (717) 782–4036. *E-mail: grieger@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Pennsylvania Program
II. Description of the Request
III. Public Comment Procedures
IV. Procedural Determinations

I. Background on the Pennsylvania Program

Section 503(a) of the Act permits a State to assume primacy for the