include new food process filing forms and a new ''smart form'' system for electronic submission of these forms. The draft guidance, when finalized, will supersede the current guidance entitled ''Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541a and FDA 2541c (Food Process Filing Forms) to FDA in Electronic or Paper Format'' (Ref. 1) when the new food process filing forms and the new ''smart form'' electronic system become operational. We intend to update the process filing regulations in 21 CFR 108.25(c)(2) and 108.35(c)(2) to specify the new form numbers, and to provide information about how to access the online system for electronic submission of these forms, when the new system becomes operational, or as soon as possible thereafter.

The draft guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to publish notice in the **Federal Register** soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we published a 60-day notice on the proposed collection of information in the **Federal Register** of September 18, 2013 (78 FR 57391).

III. Comments

Interested persons may submit either electronic comments regarding the draft guidance to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**).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. 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/FoodGuidances* or at *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the draft guidance.

V. Reference

The following reference has 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 is available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA, 2012, Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541a and FDA 2541c (Food Process Filing Forms) to FDA in Electronic or Paper Format.

Dated: January 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–00425 Filed 1–13–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1430]

Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics.'' This draft guidance responds to stakeholder requests for specific guidance on FDA's current views on how manufacturers, packers, and distributors (firms), that may either be the applicant or acting on behalf of the applicant, of prescription human and animal drug and biological products (drugs) can fulfill regulatory requirements for postmarketing submissions of interactive promotional media for their FDA-approved products. This draft guidance clarifies FDA's policies on what the Agency considers to be interactive promotional media.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 14, 2014. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; or to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding human prescription drugs: Barbara Chong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993, 301–796–1200.

Regarding prescription human biological products: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

Regarding animal prescription drugs: Dorothy McAdams, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics.''

On November 12–13, 2009, FDA held a 21 CFR part 15 public hearing entitled ''Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools'' to provide an opportunity for broad public participation and comment on the following questions that relate specifically to promotional issues:

1. For what online communications are manufacturers, packers, or distributors accountable?

2. How can manufacturers, packers, or distributors fulfill regulatory requirements (e.g., fair balance, disclosure of indication and risk information, and postmarketing submission requirements) in their internet and social media promotion, particularly when using tools that are associated with space limitations and tools that allow for real-time communications (e.g., microblogs and mobile technology)?

3. What parameters should apply to the posting of corrective information on Web sites controlled by third parties?

4. When is the use of links appropriate?

Subsequent to the live testimony heard at the part 15 public hearing, FDA received 72 comments to the docket.

This draft guidance provides FDA's recommendations to drug firms on fulfilling the regulatory requirements under 21 CFR 314.81(b)(3)(i), 21 CFR 601.12(f)(4), and 21 CFR 514.80(b)(5)(ii) for postmarketing submissions of interactive promotional media for their FDA-approved products. For the purposes of this draft guidance, the phrase ''interactive promotional media'' includes tools and technologies that often allow for real-time communications and interactions (e.g., blogs, microblogs, social networking sites, online communities, live podcasts, etc.), which firms use to promote their drugs. FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf. In determining whether the firm is accountable for a communication about its product(s), the Agency considers whether the firm, or anyone acting on its behalf, is influencing or controlling the product promotional activity or communication in whole or part.

Firms may have a variety of options for how much control they exert over activities that utilize interactive promotional media, regardless of whether the promotional activity occurs on firm sponsored venues or on third-party venues. For example, a firm may promote its products through product Web sites, discussion boards, chat rooms, or other public electronic forums that it maintains and over which it has full control. In addition, third-party sites (i.e., Web sites and other venues that are either entirely independent of a firm's control and influence or not fully controlled by a firm) also may promote a firm's products. This draft guidance outlines considerations FDA takes into account in determining when product communications using interactive technologies are subject to substantive influence by firms that market the product, therefore triggering postmarketing submission requirements.

In addition, this draft guidance provides FDA's recommendations for how firms can fulfill the regulatory requirement to submit postmarketing promotional materials to FDA in a practical manner to address the potential volume of real-time information that is continuously posted and shared through various interactive promotional media platforms.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). When finalized, it will represent the Agency's current thinking on fulfilling the regulatory requirements for postmarketing submissions of interactive promotional media for drugs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in 21 CFR 314.81(b)(3)(i), 21 CFR 601.12(f)(4), and 21 CFR 514.80(b)(5)(ii) including Forms FDA 2253 and FDA 2301, have been approved under OMB control numbers 0910–0001, 0910–0338, and 0910–0284.

III. 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. 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm,* or *http://www.regulations.gov.*

Dated: January 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–00519 Filed 1–13–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0542]

Guidance for Industry: Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled ''Guidance for Industry: Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements.'' This guidance is intended to remind manufacturers and distributors of conventional foods about the requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) regarding substances added to