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FDA is announcing the availability of a draft guidance for industry entitled ''Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal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This draft guidance provides FDA's recommendations to drug firms on fulfilling the regulatory requirements under 21 CFR 314.81(b)(3)(i), 21 CFR 601.12(f)(4), and 21 CFR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 For the purposes of this draft guidance, the phrase ''interactive promotional media'' includes tools and technologies that often allow for real-time communications and interactions (e.g., blogs,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

conventional foods, including beverages. This guidance also is intended to remind dietary supplement manufacturers and distributors that the same requirements apply to certain substances that are added to dietary supplements; namely, those that are not dietary ingredients as defined in the FD&C Act.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit electronic comments on the 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: Negash Belay, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance entitled ''Guidance for Industry: Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements.'' This guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents 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 alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of December 4, 2009 (74 FR 63759), we made available a draft guidance entitled ''Draft Guidance for Industry: Factors That Distinguish Liquid Dietary Supplements From Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods'' (draft guidance) and gave interested parties an opportunity to submit comments by February 2, 2010, for us to consider before beginning work on the final version of the guidance. Elsewhere in this issue of the **Federal Register**, we announce the availability of the final guidance, now entitled ''Guidance for Industry: Distinguishing Liquid Dietary Supplements From Beverages.''

The draft guidance included a section entitled ''Ingredients in Beverages and Other Conventional Foods are Subject to the Federal Food, Drug, and Cosmetic Act's Requirements for Substances Added to Food'' (ingredients section). The ingredients section of the draft guidance described the general requirements of the FD&C Act regarding substances added to beverages and other conventional foods. We received several comments on the draft guidance and have modified the final guidance entitled ''Guidance for Industry: Distinguishing Liquid Dietary Supplements From Beverages'' where appropriate. The modifications to the final guidance entitled ''Guidance for Industry: Distinguishing Liquid Dietary Supplements From Beverages'' include a modified version of the ingredients section, which refers to the separate guidance that is the subject of this document.

The guidance that is the subject of this document derives from the ingredients section of the draft guidance. It is intended to remind manufacturers and distributors of conventional foods about the requirements of the FD&C Act regarding substances added to conventional foods, including beverages. This guidance also is intended to remind dietary supplement manufacturers and distributors that the same requirements apply to certain substances that are added to dietary supplements; namely, those that are not dietary ingredients as defined in section 201(ff)(1) of the FD&C Act (21 U.S.C. 321(ff)(1)). We are issuing this separate guidance, in addition to referring to it within the guidance entitled ''Guidance for Industry: Distinguishing Liquid Dietary Supplements From Beverages,'' to make it more prominent and improve its accessibility to manufacturers and distributors who look for guidance on the requirements of the FD&C Act regarding substances added to conventional foods, including beverages. Although we met the procedural requirements for issuing Level 1 final guidance by making the draft guidance available for comment, we are issuing this final guidance as Level 2 guidance under 21 CFR 10.115(g)(4) because it merely summarizes long-established requirements in the FD&C Act and regulations without setting forth any new interpretations of those requirements (see 21 CFR 10.115(c)(1) to (c)(2)).

II. Comments

Interested persons may submit either electronic comments regarding the 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.*

III. Electronic Access

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

Dated: January 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–00500 Filed 1–13–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0542]

Guidance for Industry: Distinguishing Liquid Dietary Supplements From Beverages; 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 ''Distinguishing Liquid Dietary Supplements From Beverages.'' This guidance is intended to help dietary supplement and beverage manufacturers and distributors determine whether a product in liquid form is properly classified as a dietary supplement or as a beverage. This guidance describes the factors that distinguish liquid products that are dietary supplements from those that are conventional foods. Further, this guidance reminds manufacturers and distributors of dietary supplements and beverages about the requirements of the Federal Food, Drug, and Cosmetic