number 0910–0485; the collections of information in 21 CFR part 803 are approved under OMB control numbers 0910–0437 and 0910–0291; the collections of information in 21 CFR part 806 are approved under OMB control number 0910–0359; the collections of information in 21 CFR part 807 subparts B and C are approved under OMB control number 0910–0625; the collections of information in 21 CFR part 807 subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 subparts A through E are approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073; and the collections of information regarding section 513(g) of the FD&C Act (21 U.S.C. 360c(g)) are approved under OMB control number 0910–0705.

V. 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.*

Dated: February 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02573 Filed 2–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0500 (Formerly Docket No. 2004D–0042)]

Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled ''Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs.'' This revised draft guidance, when finalized, will assist manufacturers, packers, and distributors (firms) of human prescription drugs and biologics with meeting the brief summary requirement for prescription drug advertising and the requirement that adequate directions for use be included with promotional labeling for prescription drugs when print materials are directed toward consumers. FDA is also announcing the withdrawal of the draft guidance for industry entitled ''Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements.''

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 revised draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the revised draft guidance by May 11, 2015. Submit either electronic or written comments on the proposed collection of information by April 10, 2015.

ADDRESSES: Submit written requests for single copies of the revised 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, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised draft guidance document.

Submit electronic comments on the revised 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:* Julie Chronis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993–0002, 301–796–1200. *Regarding human prescription biological products:* Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs.'' This revised draft guidance updates prior FDA policy and describes the Agency's current thinking regarding the brief summary requirement for consumer-directed print prescription drug advertisements. Specifically, the revised draft guidance includes recommendations for developing a consumer brief summary and notes that, so long as firms include appropriate information in a print advertisement as outlined in the revised draft guidance, FDA does not intend to object for a failure to include certain other information.

Additionally, this revised draft guidance provides new recommendations regarding the adequate directions for use requirement for consumer-directed print promotional labeling for prescription drug products. Although the requirement in 21 CFR 201.100(d) for firms to provide adequate information for use is generally fulfilled by providing the full FDA-approved package insert (PI), this revised draft guidance provides that, in exercising its enforcement discretion, FDA does not intend to object for failure to include the full PI with consumer-directed print promotional labeling pieces if firms include the appropriate information as outlined in the revised draft guidance, *i.e.,* the same information in the consumer brief summary. This recommendation is designed to standardize the information consumers receive in print prescription drug product advertisements and promotional labeling and to make information more understandable to consumers.

FDA issued a draft guidance in the **Federal Register** of February 10, 2004 (69 FR 6308), entitled ''Brief Summary:

Disclosing Risk Information in Consumer-Directed Print Advertisements.'' FDA requested comments on whether the draft guidance provided sufficient guidance on the content of the consumer brief summary and also requested research results on potential formats for the consumer brief summary. Comments, suggestions, and research were submitted to Docket No. 2004D–0042 and were carefully analyzed and considered before developing this revised draft guidance.

This revised draft guidance incorporates information from recent social science research, clarifies the risk information that should be included in the consumer brief summary, and recommends several formatting options for this information. The revised draft guidance also recommends the use of consumer-friendly language and visual techniques to improve accessibility for consumers. Additionally, this revised draft guidance recommends that firms not disseminate the full PI to fulfill the requirements in § 201.100(d) for consumer-directed print promotional labeling for prescription drugs. Rather, the revised draft guidance recommends that firms provide the same content and format created for the consumer brief summary. FDA is issuing this revised guidance as a draft to allow for public comment on the recommendations.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). The revised draft guidance, when finalized, will represent FDA's current thinking on the brief summary and adequate directions for use requirements. 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

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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document. This revised draft guidance also refers to previously approved collection of information found in FDA regulations.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs.

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors (firms) of prescription human drug products, including biological products.

Burden Estimate: The revised draft guidance pertains to the brief summary requirement for prescription drug advertising and the requirement that adequate directions for use be included with promotional labeling for human prescription drugs when print materials are directed toward consumers.

The revised draft guidance, in part, explains FDA's current policy position that FDA does not intend to object for failure to include the entire PI to fulfill the requirements of § 201.100(d) for promotional labeling pieces directed toward consumers, if firms instead provide information on the most serious and the most common risks associated with the product, while omitting less important information. Specifically, FDA recommends that any Boxed Warning, all Contraindications, certain information regarding Warnings and Precautions (*i.e.,* the most clinically significant information from the Warnings and Precautions section of the PI, information that would affect a decision to prescribe or take a drug, monitoring or laboratory tests that may be needed, special precautions not set forth in other parts of the PI, and measures that can be taken to prevent or mitigate harm), and the most frequently occurring Adverse Reactions should be included.

Furthermore, FDA recommends that information should include the indication for the use being promoted. Information regarding patient directives (such as ''discuss with your health care provider any pre-existing conditions'' or ''tell your health care provider if you are taking any medications'') should also be included. Other types of information may be included if relevant to the drug or specific indication referred to in the promotional material(s). A statement should be included that more comprehensive information can be obtained from various sources, including the firm.

Thus, the revised draft guidance recommends that firms disclose certain information to others in place of the PI to fulfill the requirements in § 201.100(d). This ''third-party disclosure'' constitutes a ''collection of information'' under the PRA.

FDA estimates that approximately 400 firms disseminate 24,000 consumer-directed print promotional labeling pieces annually. FDA estimates that it will take firms approximately 10 hours to compile and draft the information needed to provide the information recommended in the revised draft guidance.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Adequate information for use: disclosing risk information in consumer-directed promotional labeling	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Hours per disclosure	Total hours
Disclosures Related to Adequate Information for Use (§ 201.100(d))	400	60	24,000	10	240,000

There are no capital costs or operating and maintenance costs associated with this collection of information.

This revised draft guidance also refers to previously approved collections of information found in FDA regulations with respect to the brief summary requirement. These collections of information are subject to review by OMB under the PRA. The collection of information in 21 CFR 202.1 has been approved under OMB control number 0910–0686.

III. Comments

In addition to general comments, FDA specifically requests comments on the following issues:

- In the revised draft guidance, FDA provides recommendations regarding the content and format of the consumer brief summary. Is this the most useful information for consumers to use in determining whether to take a medication or seek more information about a product, and if not, what information would be more useful?
- FDA is also interested in relevant research that has been conducted or alternative formats that were developed after we received comments on the 2004 draft guidance.
- In the revised draft guidance, FDA suggests that the adequate directions for use requirement be fulfilled by providing the consumer brief summary rather than the full PI for the product. FDA seeks comments regarding this recommendation.

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,* or *http://www.regulations.gov.*

Dated: February 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02527 Filed 2–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Joint Meeting of the Pulmonary-Allergy Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Pulmonary-Allergy Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 19, 2015, from 8 a.m. to 5 p.m.

Location: Holiday Inn Gaithersburg Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The hotel telephone number is 301–948–8900.

Contact Person: Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *PADAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committees will discuss supplemental new drug application 204275–S001, for fluticasone furoate and vilanterol inhalation powder (tradename Breo Ellipta) submitted by GlaxoSmithKline for the once daily maintenance treatment of asthma in patients 12 years of age and older. The discussion will include efficacy data, but the focus of the meeting will be safety, including the adequacy of the safety database to support approval, and whether a large safety trial to evaluate serious asthma outcomes is recommended.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 5, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 25, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 26, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Cindy Hong at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on