''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing.'' The document provides guidance to industry on the statutory requirement to submit electronically drug establishment registration and drug listing information. The guidance describes the types of information to include for purposes of drug establishment registration and drug listing and how to prepare and submit the information in an electronic format (Structured Product Labeling (SPL) files) that FDA can process, review, and archive. The burden attributed to the guidance includes the preparation of an SOP for creating and uploading the SPL file. Although most firms will already have prepared an SOP for the electronic submission of drug establishment registration and drug listing information, each year additional firms will need to create an SOP. As reflected in table 2, FDA estimates that approximately 1,000 firms will expend 40 hours to prepare, review, and approve an SOP, for a total of 40,000 hours annually.

Dated: July 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–15298 Filed 7–17–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2281]

Innovative Approaches for Nonprescription Drug Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Innovative Approaches for Nonprescription Drug Products.'' This draft guidance describes two innovative approaches that may be useful to consider for demonstrating safety and effectiveness for a nonprescription drug product in cases where the drug facts labeling (DFL) alone is not sufficient to ensure that the drug product can be used safely and effectively in a nonprescription setting: The development of labeling in addition to the DFL and the implementation of additional conditions so that consumers appropriately self-select and use the product.

DATES: Submit either electronic or written comments on the draft guidance by September 17, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–2281 for ''Innovative Approaches for Nonprescription Drug Products; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Chris Wheeler, Center for Drug Evaluation and Research, 10903 New

Hampshire Ave., Bldg. 51, Rm. 3330, Silver Spring, MD 20993, 301–796–0151.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Innovative Approaches for Nonprescription Drug Products.'' FDA approves new drugs as prescription or nonprescription drug products under section 505 of the Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355). A drug product must be dispensed by prescription if it is not safe to use except under the supervision of a practitioner licensed by law to administer the drug (*health care practitioner*) (see section 503(b)(1) of the FD&C Act (21 U.S.C. 353(b)(1)). If a drug product does not meet the criteria for prescription-only dispensing, it may be marketed as a nonprescription drug product. FDA determines whether the information submitted as part of a new drug application (NDA) for a nonprescription drug product is sufficient to ensure that the drug product is safe and effective for nonprescription use under the conditions prescribed, recommended, or suggested in its proposed labeling (see section 505(d) and 503(b)(1) of the FD&C Act.

Nonprescription drug products must comply with applicable labeling requirements for over-the-counter (OTC) drug products under 21 CFR part 201, including, but not limited to, the format and content requirements for OTC drug product labeling under § 201.66. Labeling created to satisfy the requirements in § 201.66 is commonly referred to as the DFL. The DFL is intended to help enable consumers to appropriately self-select and use the nonprescription drug product safely and effectively.

FDA has received a number of inquiries about: (1) Additional labeling, beyond the DFL, that FDA can approve for nonprescription drug products and (2) whether applications may be submitted for nonprescription drug products with one or more additional conditions that consumers must fulfill to ensure that the drug product is safe and effective for nonprescription use.

FDA is issuing this draft guidance to describe two innovative approaches to consider that may be useful for demonstrating safety and effectiveness for a nonprescription drug product in cases where the DFL alone is not sufficient to ensure that the drug product can be used safely and effectively in a nonprescription setting: (1) The development of labeling in addition to the DFL and (2) the implementation of additional conditions so that consumers appropriately self-select and use the product. The appropriateness and specific details of either of these approaches will depend on the circumstances that apply to a particular drug product. FDA believes the innovative approaches described in this draft guidance could lead to the approval of a wider range of nonprescription drug products. FDA currently intends to issue a proposed rule that provides more details regarding the use of additional conditions for nonprescription drug products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Innovative Approaches for Nonprescription Drug Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft 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 submission of NDAs under 21 CFR 314.50 to market nonprescription drug products has been approved by OMB under control number 0910–0001. In addition, OTC Drug Facts Labeling requirements under § 201.66 have been approved under OMB control number 0910–0340.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: July 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–15296 Filed 7–17–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1324]

Advisory Committee; Science Board to the Food and Drug Administration; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the renewal of the Science Board to the Food and Drug Administration (Committee) by the Commissioner of Food and Drugs (Commissioner). The Commissioner has determined that it is in the public interest to renew the Science Board to the Food and Drug Administration for an additional 2 years beyond the charter expiration date. The new charter will be in effect until June 26, 2020.

DATES: Authority for the Science Board to the Food and Drug Administration will expire on June 26, 2020, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Rakesh Raghuwanshi, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, White Oak Building 1, Rm. 3309, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4769, *rakesh.raghuwanshi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Science Board to the Food and Drug Administration. The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Science Board advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility. The Science Board shall provide advice to the Commissioner and other appropriate officials on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board will provide advice that supports the Agency in keeping pace with technical and scientific developments, including in