

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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper 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.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:**

Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific BE recommendations available to the public on FDA’s Web site at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft recommendations are posted on FDA’s Web site and

announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** on April 15, 2016 (81 FR 22283). This notice announces draft product-specific recommendations, either new or revised, that are posted on FDA’s Web site.

**II. Drug Products for Which New Draft Product-Specific BE Recommendations Are Available**

FDA is announcing the availability of a new draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

**TABLE 1—NEW DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS**

Amcinonide  
Cariprazine hydrochloride  
Cobimetinib fumarate  
Empagliflozin; Metformin hydrochloride  
Erythromycin ethylsuccinate  
Everolimus  
Flibanserin  
Fluocinonide (multiple reference listed drugs)  
Hydrocortisone  
Lesinurad  
Meloxicam  
Methylergonovine maleate  
Ombitasvir; paritaprevir; ritonavir  
Prednicarbate  
Propofol  
Pseudoephedrine hydrochloride  
Selexipag  
Tacrolimus

**III. Drug Products for Which Revised Draft Product-Specific BE Recommendations Are Available**

FDA is announcing the availability of a revised draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

**TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS**

Acetaminophen; hydrocodone bitartrate  
Albuterol sulfate  
Azelastine hydrochloride; Fluticasone propionate  
Benzoyl peroxide; Clindamycin phosphate  
Dexamethasone; Tobramycin (multiple reference listed drugs)  
Lansoprazole

**TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS—Continued**

Loteprednol Etabonate  
Loteprednol Etabonate; Tobramycin Ophthalmic  
Mesalamine (multiple reference listed drugs)  
Methylphenidate  
Morphine sulfate  
Paroxetine hydrochloride  
Pomalidomide  
Prednisolone Acetate  
Rimexolone

For a complete history of previously published **Federal Register** notices related to product-specific BE recommendations, go to <http://www.regulations.gov> and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

**IV. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 13, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–14351 Filed 6–16–16; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2016–D–1490]

**Quality Attribute Considerations for Chewable Tablets; 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 “Quality Attribute Considerations for Chewable Tablets.” This guidance describes the

Agency's thinking on the critical quality attributes that should be assessed when developing a chewable tablet dosage form and recommends that the selected acceptance criteria be appropriate and meaningful indicators of product performance throughout the shelf life of the product.

**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 comment 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 August 16, 2016.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2016-D-1490 for "Quality Attribute Considerations for Chewable Tablets." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper 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.

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:** Nallaperumal Chidambaram, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3112, Silver Spring, MD 20993-0002, 301-796-1339.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Quality Attribute Considerations for Chewable Tablets." Chewable tablets are an immediate release oral dosage form intended to be chewed and then swallowed by the patient, rather than swallowed whole. They should be designed to have a pleasant taste and be easily chewed and swallowed. Chewable tablets should be safe and easy to use in a diverse patient population, pediatric, adults, or elderly patients, who are unable or unwilling to swallow intact tablets due to the size of the tablet or difficulty with swallowing. In addition, certain tablets must be chewed before swallowing to avoid choking and to ensure the release of the active ingredient. The availability of safe, easy-to-use dosage forms is important in clinical practice, and chewable tablet formulations are available as both over-the-counter and prescription drug products.

A review of numerous applications for chewable tablet drug products revealed that in certain cases, critical quality attributes such as hardness, disintegration, and dissolution were not given as much consideration as may have been warranted. This draft guidance describes the critical quality attributes that should be assessed when developing a chewable tablet dosage form. No single quality characteristic should be considered sufficient to control the performance of a chewable tablet. Instead, the goal should be to develop the proper combination of these attributes to ensure the performance of the chewable tablet for its intended use.

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 Quality Attribute Considerations for Chewable Tablets. 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.

## II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 investigational new drug applications is approved under OMB control number 0910–0014; the collection of information (including prescription drug labeling) in new drug applications and abbreviated new drug applications, as well as supplements to these applications, is approved under OMB control number 0910–0001; the collection of biologics license applications is approved under OMB control number 0910–0338; and the format and content of prescription drug labeling is approved under OMB control number 0910–0572.

## III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 13, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–14354 Filed 6–16–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2013–N–0717]

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaigns**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by July 18, 2016.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–0753. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### **Evaluation of FDA's General Market Youth Tobacco Prevention Campaigns—OMB Control Number 0910–0753—Revision**

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors. Section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) supports the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA is currently developing and implementing youth-targeted public education campaigns to help prevent tobacco use among youth and thereby reduce the public health burden of tobacco. The campaigns feature televised advertisements along with complementary ads on radio, on the Internet, in print, and through other forms of media.

Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions. Comprehensive evaluation of FDA's public education campaigns will be used to document whether the intended audience is aware of and understands campaign messages; and whether campaign exposure influences beliefs about tobacco, susceptibility to tobacco use, and tobacco use behavior. All of the

information collected is integral to that evaluation.

FDA is in the process of conducting three studies to evaluate the effectiveness of its youth tobacco prevention campaigns: (1) An outcome evaluation study of its General Market Youth Tobacco Prevention Campaign, (2) an outcome evaluation of the Rural Male Youth Smokeless Tobacco Campaign, and (3) a media tracking survey. The timing of these studies follows the multiple, discrete waves of media advertising planned for the campaigns.

#### *Evaluation of the General Market Youth Tobacco Prevention Campaign*

The General Market Youth Tobacco Prevention Campaign targets youth who are at-risk for smoking, or who have experimented with but not progressed to regular smoking. The outcome evaluation of the campaign consists of an initial baseline survey of youth aged 11 to 16 before campaigns launch, followed by a number of longitudinal follow-up surveys of the same youth at approximate 8 month intervals. To date, the baseline and three follow-up surveys have been conducted. A baseline survey was also conducted with the parent or legal guardian of each youth, to collect data on household characteristics and media use. Because the cohort aged over the study period, data have been collected from youth aged 11 to 18. Information has been collected about youth awareness of and exposure to campaign advertisements and about youth knowledge, attitudes, and beliefs related to tobacco use. In addition, the surveys have measured tobacco use susceptibility and current use. Information has been collected on demographic variables including age, sex, race/ethnicity, grade level, and primary language.

#### *Evaluation of the Rural Male Youth Smokeless Tobacco Campaign*

Baseline data collection for the Rural Male Youth Smokeless Campaign evaluation will begin in January 2016. The three follow up surveys will begin in August 2016, March 2017, and October 2017. The evaluation of the Rural Male Youth Smokeless Campaign differs from the General Market Campaign evaluation, in that only males in the age range will be considered eligible.

#### *Media Tracking Survey*

The media tracking survey consists of assessments of youth aged 13 to 18 conducted periodically during the campaign period. The tracking survey assesses awareness of the campaign and