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 guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, 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 document entitled ''Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Guidance for Industry.'' The guidance describes the expedited programs available to sponsors of regenerative medicine therapies for serious or life-threatening diseases or conditions (referred to in the guidance as serious conditions), including those products designated as RMATs; provides information about the provisions in the 21st Century Cures Act (Cures Act) (Pub. L. 114–225) regarding the use of the accelerated approval pathway for regenerative medicine therapies that have been granted designation as an RMAT; describes how CBER will encourage flexibility in clinical trial design to facilitate the development of data to demonstrate the safety and effectiveness of regenerative medicine therapies that are being developed to address unmet needs in patients with serious conditions; and describes the opportunities for sponsors of regenerative medicine therapies to interact with CBER review staff.

In the **Federal Register** of November 17, 2017 (82 FR 54385), FDA announced the availability of the draft guidance of the same title dated November 2017. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated November 2017.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a document entitled ''Evaluation of Devices Used with Regenerative Medicine Advanced Therapies; Guidance for Industry.''

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Expedited Programs for Regenerative Medicine Therapies for Serious Conditions.'' 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 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 collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information regarding formal meetings described in the draft guidance, ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products,'' have been approved under OMB control number 0910–0429; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information for expedited programs in ''Guidance for Industry: Expedited Programs for Serious Conditions—Drugs and Biologics,'' have been approved under OMB control number 0910–0765; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

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

Dated: February 13, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02691 Filed 2–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–0065]

Competitive Generic Therapies; 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 ''Competitive Generic Therapies.'' On August 18, 2017, the FDA Reauthorization Act of 2017 (FDARA), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), was signed into law. Under FDARA, a section was added to the FD&C Act that established a new process to designate, and expedite the development and review of, certain drugs intended for submission or submitted in an abbreviated new drug application (ANDA) and for which there is ''inadequate generic competition.'' This draft guidance provides a description of the process that applicants should follow to request designation of a drug as a competitive generic therapy (CGT) and the criteria for designating a drug as a CGT. This draft guidance also includes information on the actions FDA may take to expedite the development and review of an ANDA for a drug designated as a CGT. This draft guidance also provides information on how FDA implements the statutory provisions providing for a 180-day exclusivity period for certain first approved applicants that submit ANDAs for drugs designated as CGTs.

DATES: Submit either electronic or written comments on the draft guidance by April 22, 2019 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–2019–D–0065 for ''Competitive Generic Therapies.'' 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: Susan Levine, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1674, Silver Spring, MD 20993–0002, 240–402–7936.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Competitive Generic Therapies.'' On August 18, 2017, FDARA (Pub. L. 115–52) was signed into law. As part of FDARA, the Generic Drug User Fee Amendments were reauthorized (Title III) to continue timely access to high-quality affordable generic medicines. FDARA also created other enhancements associated with generic drugs. Specifically, section 803 of FDARA amended the FD&C Act to add section 506H (21 U.S.C. 356h), which established a new process to designate, and expedite the development and review of, certain drugs intended for submission or submitted in an ANDA and for which there is ''inadequate generic competition.''

FDA recognizes that various factors may influence a generic drug applicant's decision to develop a certain drug. For instance, some drugs may not attract a high level of interest from generic drug applicants if there is a limited market for the products and/or if the products are more difficult to develop. Nevertheless, these drugs can play an important role in diagnosing, treating, and preventing various types of diseases or conditions, and incentivizing generic competition for these products can help ensure patients have access to the medicines they need. The provisions associated with CGTs are intended to incentivize effective development, efficient review, and timely market entry for drugs for which there is inadequate generic competition.

This guidance provides a description of the process that applicants should follow to request designation of a drug as a CGT and the criteria for designating a drug as a CGT. This guidance also includes information on the actions FDA may take to expedite the development and review of ANDAs for drugs designated as CGT. These actions may help to clarify the regulatory expectations for a particular drug, assist applicants in developing a more complete submission, and ultimately promote a more efficient and effective ANDA review process and help reduce the number of review cycles necessary to obtain ANDA approval.

This guidance also provides information on how FDA implements the statutory provisions providing for a 180-day exclusivity period for certain first approved applicants that submit ANDAs for CGTs. FDARA created a new type of 180-day exclusivity, different from 180-day patent challenge exclusivity, for the first approved applicant of a drug with a CGT designation for which there were no unexpired patents or exclusivities listed in the Orange Book at the time of original submission of the ANDA. This new 180-exclusivity under FDARA (''CGT exclusivity'') is intended to incentivize competition for drugs that are not protected by patent or exclusivity and for which there is inadequate generic competition.

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 ''Competitive Generic Therapies.'' 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 collections of information in 21 CFR 314.94, including the submission of ANDAs and designations such as CGT product development, have been approved under OMB control number 0910–0001 (including 0910–0338 for Form FDA 356h). The collections of information associated with product development meetings, presubmission meetings, and mid-review cycle meetings between applicants and FDA have been approved under OMB control number 0910–0797.

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: February 12, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02598 Filed 2–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1093]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Additive Petitions and Investigational Food Additive Exemptions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 March 21, 2019.

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.* All comments should be identified with the OMB control number 0910–0546. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Food Additive Petitions and Investigational Food Additive Exemptions—21 CFR 570.17, 571.1, and 571.6

OMB Control Number 0910–0546—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation which prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) of the FD&C Act (21 U.S.C. 348(b)) specifies the information that must be submitted by a petitioner to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provisions of § 409 of the FD&C Act, we issued procedural regulations under 21 CFR part 571. These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the FD&C Act. The regulations add no substantive requirements to those indicated in the FD&C Act, but attempt to explain these requirements and provide a standard format for submission to speed processing of the petition. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in 21 CFR parts 501, 573, and 579. The labeling regulations are considered by FDA to be cross-referenced to § 571.1, which is the subject of this same OMB clearance for food additive petitions.

Regarding the investigational use of food additives, § 409(j) of the FD&C Act (§ 409(j)) (21 U.S.C. 348(j)) provides that any food additive, or any food bearing or containing such an additive, may be exempted from the requirements of this section if intended solely for investigational use by qualified experts. Investigational use of a food additive is typically to address the safety and/or intended physical or technical effect of the additive.

To implement the provisions of § 409(j), we issued regulations under 21 CFR 570.17. These regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broad terms by the FD&C Act. Labeling requirements for investigational food additives are also set forth in various regulations contained in 21 CFR 501. The labeling regulations are considered by FDA to be cross-referenced to § 570.17, which is the subject of this same OMB clearance for investigational food additive files.

The information collected is necessary to protect the public health. We use the information submitted by food manufacturers or food additive manufacturers to ascertain whether the data establish the identity of the substance, justify its intended effect in/on the food, and establish that its intended use in/on food is safe.

Description of Respondents: Respondents to this collection of information are food manufacturers or food additive manufacturers.

In the **Federal Register** of August 3, 2018 (83 FR 38149), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows: