TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests for nonbinding feedback after certain FDA inspections of device establishments	220	1	220	500	110,000

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

Our estimate that 220 respondents per year will request nonbinding feedback as described in the draft guidance is based on recent inspectional data. Based on the recommendations in the guidance and our experience with similar information collections, we believe it will take approximately 500 hours to complete a request for nonbinding feedback. Therefore, we estimate the burden of this information collection to be 110,000 hours.

Dated: February 12, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02620 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–2017–D–6159]

Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; 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 final guidance entitled ''Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Guidance for Industry.'' The guidance document provides sponsors engaged in the development of regenerative medicine therapies for serious or life-threatening diseases or conditions with FDA's recommendations on the expedited development and review of these therapies. The guidance describes the expedited programs available to sponsors of regenerative medicine therapies for serious or life-threatening diseases or conditions, including those products designated as regenerative advanced therapies (which FDA refers to as ''regenerative medicine advanced therapy'' (RMAT) designation). The guidance also describes considerations in the clinical development of regenerative medicine therapies and opportunities for sponsors of regenerative medicine therapies to interact with the Center of Biologics Evaluation and Research (CBER) review staff.

The guidance announced in this notice finalizes the draft guidance of the same title dated November 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on February 19, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2017–D–6159 for ''Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Guidance for Industry.'' 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 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]

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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: