Our estimate that 220 respondents per year will request nonbinding feedback as described in the draft guidance is based on recent inspectional data.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.


Lowell J. Schiller,
Acting Associate Commissioner for Policy.

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; Availability” 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The guidance announced in this notice finalizes the draft guidance of the same title dated November 2017.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 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 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 publicy 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 docket, 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.

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.

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.

Table 1—Estimated Annual Reporting Burden

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requests for nonbinding feedback after certain FDA inspections of device establishments</td>
<td>220</td>
<td>1</td>
<td>220</td>
<td>500</td>
<td>110,000</td>
</tr>
</tbody>
</table>

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

Lowell J. Schiller,
Acting Associate Commissioner for Policy.

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

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