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.govinfo.gov/content/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.

Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.

Table 1—List of Information Collections Approved by OMB

<table>
<thead>
<tr>
<th>Title of collection</th>
<th>OMB control number</th>
<th>Date approval expires</th>
</tr>
</thead>
<tbody>
<tr>
<td>Web-Based Pilot Survey to Assess Allergy to Cosmetics in the United States</td>
<td>0910–0881</td>
<td>1/31/2021</td>
</tr>
<tr>
<td>Postmarket Surveillance of Medical Devices</td>
<td>0910–0449</td>
<td>11/30/2022</td>
</tr>
<tr>
<td>Administrative Procedures for Clinical Laboratory Improvement Amendments Categorization</td>
<td>0910–0607</td>
<td>11/30/2022</td>
</tr>
</tbody>
</table>


Lowell J. Schiller,
Principal Associate Commissioner for Policy.

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ASSURANCES: 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 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–2008–D–0205 for “Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications; 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.


Lowell J. Schiller,
Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications; 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 “Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs); Guidance for Industry.” The guidance document provides sponsors of human gene therapy INDs with recommendations regarding CMC information to be submitted in an IND. The guidance document informs sponsors how to provide sufficient CMC information required to assure product safety, identity, quality, purity, and strength (including potency) of the investigational product. The guidance applies to human gene therapy products and to combination products that contain a human gene therapy in combination with a drug or device.