When paying by wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. For international wire transfers, please inquire with the financial institutions prior to submitting the payment. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREATS NYC, 33 Liberty St., New York, NY 10045. Account Name: Food and Drug Administration, Account No.: 75606099, Routing No.: 021030004, Swift No.: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This phone number is only for questions about courier delivery.)

The tax identification number of FDA is 53–0196965. (Note: In no case should the payment for the fee be submitted to FDA with the invoice.)

VI. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in 21 CFR 1.725. If FDA does not receive an application fee with an application for recognition, the application will be considered incomplete and FDA will not review the application. If a recognized accreditation body fails to submit its annual user fee within 30 days of the due date, we will suspend its recognition. If the accredited accreditation body fails to submit its annual user fee within 90 days of the due date, we will revoke its recognition.

If an accredited accreditation body fails to submit its recognition within 90 days of the due date, we will suspend its accreditation. If the recognized accreditation body fails to submit its recognition within 90 days of the due date, we will revoke its recognition.

When paying by check, bank draft, or U.S. postal money order, please include the invoice number. Also write the FDA post office box number (P.O. Box 979108) on the enclosed check, bank draft, or money order. Mail the payment and a copy of the invoice to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000.
TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

<table>
<thead>
<tr>
<th>Title of collection</th>
<th>OMB control No.</th>
<th>Date approval expires</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual Patient Expanded Access Applications</td>
<td>0910–0814</td>
<td>5/31/2022</td>
</tr>
<tr>
<td>Electronic Forma for Submissions; Promotional labeling and Advertising Materials for Human Prescription</td>
<td>0910–0870</td>
<td>5/31/2022</td>
</tr>
<tr>
<td>Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation</td>
<td>0910–0456</td>
<td>6/30/2022</td>
</tr>
<tr>
<td>Electronic Submission of Medical Device Registration and Listing</td>
<td>0910–0625</td>
<td>6/30/2022</td>
</tr>
<tr>
<td>Antimicrobial Animal Drug Distribution Reports and Recordkeeping</td>
<td>0910–0659</td>
<td>6/30/2022</td>
</tr>
</tbody>
</table>

Dated: July 16, 2019.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. FDA–2008–N–0424]

Final Guidance for Industry and FDA Staff on Postmarketing Safety Reporting for Combination Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry and FDA staff entitled “Postmarketing Safety Reporting for Combination Products Guidance for Industry and FDA Staff.” The guidance describes and explains the final rule on postmarketing safety reporting (PMSR) for combination products, issued on December 20, 2016, and provides recommendations for complying with the PMSR requirements as well as hypothetical scenarios that illustrate how to comply with certain PMSR requirements.


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: 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 below (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–N–0424 for “Postmarketing Safety Reporting for Combination Products Guidance for Industry and FDA Staff.” 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 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 http://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 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 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 a single hard copy of the guidance document entitled “Postmarketing Safety Reporting for Combination