TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
117.126(c) and 117.170(d); food safety plan and re-analysis.	46,685	1	46,685	110	5,135,350
117.136; assurance records	16,285	1	16,285	0.25 (15 minutes)	4,071
117.145(c); monitoring records	8,143	730	5,944,390	0.05 (3 minutes)	297,220
117.150(d); corrective actions and corrections records.	16,285	2	32,570	1	32,570
117.155(b); verification records	8,143	244	1,986,892	0.05 (3 minutes)	99,345
117.160; validation records	3,677	6	22,062	0.25 (15 minutes)	5,515
117.475(c)(7)-(9); supplier records	16,285	10	162,850	4	651,400
117.180(d); training records for preventive controls qualified individual.	46,685	1	46,685	0.25 (15 minutes)	11,671
Total					6,237,142

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
117.201(e); disclosure of food manufacturing facility address.	37,134	1	37,134	0.25 (15 minutes)	9,284

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

These figures are based on our regulatory impact analysis in support of the final rule on preventive controls for human food, which published in the **Federal Register** of September 17, 2015 (80 FR 55908). Using Agency data, we estimated the number of food facilities that we believe are subject to the regulations. We base our estimate of the time necessary for the individual reporting, recordkeeping, and third-party disclosure activities on our experience with similar information collections.

Dated: May 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–11801 Filed 5–31–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1041]

Development of a Shared System Risk Evaluation and Mitigation Strategy; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Development of a Shared System REMS.'' This draft guidance provides recommendations on the development of a shared system risk evaluation and mitigation strategy (REMS) for multiple prescription drug (including biological) products. This guidance describes some of the possible benefits of a shared system REMS, and provides general principles and recommendations to assist industry with the development of these programs.

DATES: Submit either electronic or written comments on the draft guidance by July 31, 2018 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–2018–D–1041 for ''Development of a Shared System REMS; Draft Guidance for Industry; Availability.'' 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: Lubna Merchant, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4418, Silver Spring, MD 20993–0002, 301–796–5162, email: *Lubna.Merchant@fda.hhs.gov*; or Stephen Ripley, 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 draft guidance for industry entitled ''Development of a Shared System REMS.'' This guidance describes some of the possible benefits of shared system REMS, and provides general principles and recommendations to assist industry with the development of these programs.

Section 505–l(i)(l)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355–1((i)(1)(B)) requires that a holder of an abbreviated new drug application (ANDA) approved under section 505(j) use a ''single, shared system'' with the reference listed drug (RLD) for any REMS with elements to assure safe use (ETASU) unless FDA waives this requirement.

The requirement under section 505–1(i)(1)(B) regarding a ''single, shared system'' only applies to ANDAs. However, FDA recognizes that it may be in the interest of public health to have a shared system REMS in other cases because it may increase efficiencies for applicants and stakeholders. A shared system REMS can encompass multiple prescription drug products and can be developed and implemented jointly by two or more applicants. It can be a program shared by a drug that is the subject of an ANDA and the listed drug, as required in section 505–1(i)(1)(B) (described above). It can also involve multiple new drug applications, ANDAs, or biologics license applications, approved under section 505(b)(1), (b)(2), or (j) of the FD&C Act (21 U.S.C. 355(b)(1), (b)(2) or (j)) or section 351(a) or (k) of the PHS Act (42 U.S.C. 262(a) or (k)), respectively, that form a shared system voluntarily.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance entitled ''Waivers of the Single, Shared System REMS Requirement.'' Among other things, that guidance describes how FDA will consider granting a waiver of the requirement in section 505–1(i) of the FD&C Act that the applicant for an ANDA and its RLD use a single, shared system for REMS with ETASU.

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 ''Development of a Shared System REMS.'' 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 collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The preparation and submission of a drug master file (as described in 21 CFR 314.420) by applicants for their shared system REMS submissions has been approved under OMB control number 0910–0001. In accordance with the PRA, before publication of the final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to previously approved collections of information found in FDA regulations.

III. Electronic Access

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

Dated: May 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–11783 Filed 5–31–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Pain Management Best Practices Inter-Agency Task Force; Amendment

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice; amendment.