3600, *Elaine.Lippmann@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FDA is announcing the availability of a draft guidance for industry entitled ''Waivers of the Single, Shared System REMS Requirement.'' This guidance describes how the Agency intends to consider granting a waiver of the requirement in section 505–1(i) of the FD&C Act (21 U.S.C. 355–1(i)) that the applicant for an ANDA and its RLD use a SSS for a required REMS with ETASU.

Section 505–l(i)(l)(B) of the FD&C Act requires that a holder of an ANDA under section 505(j) use a ''single, shared system'' with the RLD for any ETASU, unless FDA waives this requirement. The statute permits a waiver of the SSS requirement if FDA finds that (1) ''the burden of creating a [SSS] outweighs the benefit of a single, system, taking into consideration the impact on health care providers, patients, the applicant for the [ANDA], and the holder of the reference drug product,'' or (2) an aspect of the ETASU for the applicable listed drug is claimed by an unexpired patent or trade secret and the ANDA applicant certifies that it sought a license for use of the aspect, but was unable to obtain one. If a waiver of the SSS requirement is granted, the ANDA may use ''a different, comparable aspect of the [ETASU],'' instead of participating in a SSS with the RLD.

This guidance is intended to explain the factors FDA will consider in evaluating a request for waiver of the SSS requirement and provide recommendations to ANDA applicants regarding the submission and content of waiver requests. The guidance also addresses FDA's interpretation of what constitutes a different, comparable aspect of the ETASU as described in section 505–1(i)(1)(B).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Waivers of the Single, Shared System REMS Requirement.'' 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This draft guidance refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA)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 waiver requests (as described in 21 CFR 314.90 for new drug application applicants and 314.99(b) for ANDA applicants) 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 *https://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. 2018–11784 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–2011–N–0920]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements associated with current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food.

DATES: Submit either electronic or written comments on the collection of information by July 31, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 31, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of July 31, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2011–N–0920 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Current Good Manufacturing Practice and Hazard Analysis, and Risk-Based Preventive Controls for Human Food—21 CFR Part 117

OMB Control Number 0910–0751—Extension

This information collection supports FDA regulations. As amended by the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), the Federal Food, Drug, and Cosmetic Act (FD&C Act) enables the Agency to better protect the public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production. Specifically, section 418 of the FD&C Act (21 U.S.C. 350g) sets forth requirements for hazard analysis and risk-based preventive controls for facilities that produce food for human consumption. To implement these provisions, regulations were codified under 21 CFR part 117—Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. The regulations establish requirements for a written food safety plan; hazard analysis preventive controls; monitoring; corrective actions and corrections; verification; supply-chain program; recall plan; and associated records, and became effective November 16, 2015. Currently, we continue to evaluate burden associated with the information collection requirements; however, for purposes of extending the information collection we retain the currently approved figures as shown below.

Our estimate of the burden for the information collection is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
117.201(e); qualified facility	37,134	0.5	18,567	0.5 (30 minutes)	9,284

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

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