''burden'' under 5 CFR 1320.3(b)(2). FDA understands that maintaining records of prescriptions for compounded drug products is part of the usual course of the practice of compounding and selling drugs and is required by States' pharmacy laws and other State laws governing record keeping by health care professionals and health care facilities.

Under the guidance, licensed pharmacists and licensed physicians should also maintain records of the calculations performed to determine the limited quantities of drug products compounded before the receipt of valid prescription orders under the enforcement policy described in section III.B.2 of this guidance and section 503A(a)(2) of the FD&C Act. These records should clearly reflect the quantity of a particular drug product compounded in advance of receiving prescription orders for identified individual patients that the compounder has kept on hand as stock for distribution, and the basis for the quantity the compounder kept in stock. Under the enforcement policy described in section III.B.2 of this guidance, this would include the quantity of the drug product distributed under prescription orders for identified individual patients during the reference period that the licensed pharmacist or licensed physician selected (*i.e.,* a 30-day period within the last year).

We estimate that annually a total of approximately 10,332 licensed pharmacists and licensed physicians (''number of recordkeepers'' in table 2) will maintain approximately 103,320 records (''total annual records'' in table 2). We estimate that maintaining the records will take approximately 5 minutes per record.

FDA estimates the burden of this collection of information as follows:

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

Type of reporting	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Consultation between the licensed pharmacist or licensed physician and the prescriber and adding a notation to document the prescriber's determination that a compounded drug is necessary for an identified patient.	3,444	50	172,200	0.083 (5 minutes).	14,350

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of reporting	Number of record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records of calculations performed to determine ''limited quantities''.	10,332	10	103,320	0.083 (5 minutes).	8,610

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

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* or *http://www.regulations.gov.*

Dated: April 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08877 Filed 4–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0427]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Inspection by Accredited Persons Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 18, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0510. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002—OMB Control Number 0910–0510—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250) was signed into law on October 26, 2002. Section 201 of MDUFMA added a new paragraph (g) to section 704 of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons) to conduct inspections of eligible manufacturers of class II or class III devices. FDA's guidance document entitled ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002;

Accreditation Criteria'' provides information for those interested in participating in this voluntary program.

In the **Federal Register** of October 21, 2015 (80 FR 63806), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Request for accreditation	1	1	1	80	80

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

Dated: April 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08893 Filed 4–15–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1109]

Tobacco Farm Site Tours Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is announcing an invitation for participation in its voluntary Tobacco Farm Site Tours Program. This program is intended to give CTP staff an opportunity to visit farms that grow tobacco for sale to tobacco product manufacturers in order to gain a better understanding of tobacco farming and the processes involved in curing and preparing tobacco intended for sale to tobacco product manufacturers. This program is not an FDA regulatory inspection, and tobacco farms are not regulated entities unless they are also a tobacco product manufacturer or controlled by a tobacco product manufacturer. The purpose of this notice is to invite parties interested in participating in the Tobacco Farm Site Tours Program to submit requests to CTP.

DATES: Submit either an electronic or written request for participation in this program by June 17, 2016. See section IV of this document for information on requests for participation.

ADDRESSES: If your farm is interested in offering a site visit, please submit a request either electronically to *http://www.regulations.gov* or in writing to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Allison Hoffman, Office of Science, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 5426, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) into law, amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and giving FDA authority to regulate tobacco product manufacturing, distribution, and marketing.

CTP's Office of Science is conducting the Tobacco Farm Site Tours Program to provide its staff an opportunity to visit farms that grow tobacco for sale to tobacco product manufacturers (a ''tobacco product manufacturer'' is defined as any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product, or imports a finished tobacco product for sale or distribution in the United States (section 900(20) of the FD&C Act (21 U.S.C. 387(20))). Although farms that grow tobacco are not FDA-regulated entities unless they are also a tobacco product manufacturer or controlled by a tobacco product manufacturer (see section 901(c)(2) of the FD&C Act (21 U.S.C. 387a(c)(2))), tobacco farm site visits will aid the Agency in gaining a better understanding of tobacco farming and the processes involved in curing and preparing tobacco leaf intended for sale to tobacco product manufacturers. The goal for the Tobacco Farm Site Tours Program is for CTP staff to gain firsthand exposure to tobacco farming practices, including cultivation, harvesting, curing, and preparation for sale of tobacco leaf to tobacco product manufacturers.

II. Description of Tobacco Farm Site Tours Program

In the Tobacco Farm Site Tours Program, small groups of CTP staff plan to observe the operations of farms that grow tobacco for sale to tobacco product manufacturers. Please note that FDA does not regulate these farms and the Tobacco Farm Site Tours Program is not an inspection of facilities to determine compliance with the FD&C Act; rather, this program is meant to educate CTP staff and improve their understanding of tobacco farming. It is anticipated that the tobacco farm site tours will take place in the fall of 2016.

III. Site Selection

CTP hopes to be able to tour small, medium, and large farms, and farms that grow tobacco for different kinds of tobacco products. Final site selections will be based on the availability of funds and resources for the relevant fiscal year as well as the desire to visit a wide variety of types of tobacco farms. FDA plans on visiting nine or fewer farms. All FDA travel expenses associated with the farm site tours will be the responsibility of FDA.

IV. Requests for Participation

To aid in site selection, your request for participation should include the following information:

- A description of your farm, including the size of the farm;
- A list of the type(s) of tobacco grown and the kinds of tobacco product manufacturers to whom you sell tobacco;
- The physical address(es) of the site(s) for which you are submitting a request; and
- A proposed 1-day tour agenda.

Identify requests for participation with the docket number found in brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.