Commissioner of Food and Drugs' authority provided in section 1003(d)(2)(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(c)).

Protecting the nation's food and agriculture supply against intentional contamination and other emerging threats is an important responsibility shared by Federal, State, local, tribal, and territorial governments as well as private sector partners. On January 4, 2011, the President signed FSMA. FSMA focuses on ensuring the safety of the U.S. food supply by shifting the efforts of Federal regulators from response to prevention, and recognizes the importance of strengthening existing collaboration among all stakeholders to achieve common public health and security goals. FSMA identifies some key priorities for working with partners in areas such as reliance on Federal, State, and local agencies for inspections; improving foodborne illness surveillance; and leveraging and enhancing State and local food safety and defense capacities. Section 108 of FSMA (NAFDS) requires HHS and the USDA, in coordination with the DHS, to work together with State, local, territorial, and tribal governments-to monitor and measure progress in food defense.

In 2015, the initial NAFDS Report to Congress detailed the specific Federal response to food and agriculture defense goals, objectives, key initiatives, and activities that HHS, USDA, DHS, and other stakeholders planned to accomplish to meet the objectives outlined in FSMA. The NAFDS charts a direction for how the Federal Agencies, in cooperation with State, local, territorial, and tribal governments and private sector partners, protect the nation's food supply against intentional contamination. Not later than 4 years after the initial NAFDS Report to Congress (2015), and every 4 years thereafter (*i.e.,* 2019, 2023, 2017, etc.), HHS, USDA, and DHS are required to revise and submit an updated report to the relevant committees of Congress.

HHS/FDA is primarily responsible for obtaining the information from Federal and State, local, territorial, and tribal partners to complete the NAFDS Report to Congress. An interagency working group will conduct the survey and collect and update the NAFDS as directed by FSMA, including developing metrics and measuring progress for the evaluation process.

The proposed survey of Federal and State partners will be used to determine what food defense activities, if any, Federal and/or State Agencies have completed (or are planning) from 2015 to 2019. Planning for the local, territorial, and tribal information collections will commence after the collection and reporting of Federal and State Agency level data.

This survey will be repeated approximately every 2 to 4 years, as described in section 108 of FSMA, NAFDS, for the purpose of monitoring progress in food and agricultural defense by government agencies.

A purposive sampling strategy will be employed, such that the government agencies participating in food and agricultural defense cooperative agreements with FDA (22 State Agencies) and USDA (27 State Agencies) will be asked to respond to the voluntary survey. Food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdiction will be identified and will receive an emailed invitation to complete the survey online; they will be provided with a web link to the survey. The survey will be conducted electronically on the *FDA.gov* web portal, and results will be analyzed by the interagency working group.

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
State Survey	49	1	49	0.33 (20 minutes)	16.17

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

The total burden for this collection of information, therefore, is 16.17 hours.

The FDA Office of Partnerships reviewed the questionnaire and provided the amount of time to complete the survey. The total burden is based on our previous experiences conducting surveys.

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06135 Filed 3–27–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1267]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Compounded Drug Products That Are Essentially Copies of an Approved Drug Product Under Section 503B of the Federal Food, Drug, and Cosmetic Act

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 April 27, 2018.

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–NEW and title ''Guidance for Industry on Compounded Drug Products That Are Essentially Copies of an Approved Drug Product Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' Also include the FDA docket number found in brackets in the heading of this document.

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

I. Background

Guidance for Industry on Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–NEW

This information collection supports the above captioned Agency guidance. Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b) describes conditions that must be met in order for compounded drugs to receive exemptions from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)) and section 582 (21 U.S.C. 360eee–1) (concerning drug supply chain security requirements). One of the conditions that must be met for a compounded drug product to qualify for the exemptions under section 503B of the FD&C Act is that ''the drug is not essentially a copy of one or more approved drugs'' (section 503B(a)(5)).

According to section 503B(d)(2) of the FD&C Act, a compounded drug is essentially a copy of an approved drug when it (1) is identical or nearly identical to an approved drug that is not on FDA's drug shortage list at the time the drug is compounded, distributed, and dispensed; or to a non-prescription drug product marketed without an approved application, or (2) contains the same bulk drug substance as an approved drug or a non-prescription drug product marketed without an approved application, unless there is a change that produces a clinical difference for an individual patient as determined by the prescribing practitioner between the compounded drug and the approved drug (see section 503B(d)(2)(A) and (B)).

Under the policy proposed in the draft guidance, if an outsourcing facility intends to rely on a prescriber determination made under section 503B(d)(2)(B) to establish that a compounded drug is not essentially a copy of an approved drug, the outsourcing facility should ensure that the determination is documented on the prescription or order (which may be a patient-specific prescription or a non-patient specific order) for the compounded drug.

If a prescription or order does not make clear that the determination required by section 503B(d)(2)(B) has been made, the outsourcing facility may contact the prescriber or health care facility, and if the prescriber or health care facility contact confirms it, make a notation on the prescription or order that the prescriber has determined that the compounded product contains a change that produces a clinical difference for patient(s). The date of the conversation with the health care facility contact or prescriber, and the name of the individual providing the determination, should be included on the prescription or order.

In addition, if the outsourcing facility compounded a drug that is identical or nearly identical to an approved drug product that appeared on FDA's drug shortage list, the outsourcing facility should maintain documentation (*e.g.,* a notation on the order for the compounded drug) regarding the status of the drug on FDA's drug shortage list at the time of compounding, distribution, and dispensing.

An outsourcing facility should also maintain records of prescriptions or orders including notations that a prescriber has determined that the compounded drug has a change that produces a clinical difference for an individual patient. Because the time, effort, and financial resources necessary to comply with this collection of information would be incurred by licensed pharmacists and licensed physicians in the normal course of their activities, it is excluded from the definition of ''burden'' under 5 CFR 1320.3(b)(2).

II. Paperwork Reduction Act of 1995

In the **Federal Register** of July 11, 2016 (81 FR 44879), we published a notice of availability for the draft guidance, including an analysis of estimated burden under the PRA, and invited public comment of the proposed information collection. Several comments were received and are discussed below.

III. Comments

Issue One: Several commenters said it would be unnecessarily burdensome for prescribers to document the clinical need for a compounded drug, and that a pharmacist, nurse, or other clinician choosing to source compounded drugs from an outsourcing facility should be able to assess the clinical need for the compounded drug.

FDA Response to Issue One: Under section 503B(d)(2), if a drug is not identical or nearly identical to an approved drug or a covered over-the-counter monograph (OTC) drug, and a component of the compounded drug is a bulk drug substance that is a component of an approved drug or a covered OTC drug, then the drug is essentially a copy and may not be compounded under section 503B unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug. If a prescription or order already documents the determination of clinical difference, there is no additional documentation burden for the compounder. If a prescription or order does not make clear that the determination of clinical difference required by the statute has been made, the compounder may contact the prescriber, and if the prescriber confirms it, make a notation on the prescription or order that the compounded product contains a change that makes a clinical difference for the patient. The date of the conversation with the health care facility or prescriber, and the name of the individual providing the determination, should be included on the prescription or order. FDA estimates this contact will take 3 minutes and should not present significant burden. Maintaining prescription records that may include such notations should not present any additional burden, as FDA understands that maintaining records of prescriptions or orders for compounded drug products is part of the usual course of the practice of compounding and selling drugs.

FDA also notes that for non-patient specific orders, the guidance states that an outsourcing facility may obtain a statement from the prescribing practitioner or a person able to make a representation for the health care practitioner. For example, a pharmacy manager could order a compounded drug and document on the order that the compounded drug will only be administered to patients for whom the prescriber determines that this formulation will produce a clinical difference.

Issue Two: At least two commenters raised concerns that documentation of the prescriber determination of clinical

difference could lead to liability concerns (*e.g.,* for a pharmacy manager who makes representations to an outsourcing facility about how a drug will be used) and scope of practice concerns (if a doctor concludes he or she should not be bound by the representations).

FDA Response to Issue Two: For certain drugs, one of the conditions to qualify for exemptions under section 503B is that there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug. If a pharmacy manager does not wish to document on the order that such a drug will only be administered after an appropriate prescriber determination, the manager could ask the prescriber to provide documentation. If a prescriber, or person able to make a representation for a prescriber, refuses to confirm that a compounded drug produces a clinical difference for a patient, the compounded drug may be considered ''essentially a copy'' of the commercially-available product. The outsourcing facility may decide in this scenario to not compound the drug.

Issue Three: At least one commenter recommended that the guidance requires practitioners to provide additional details regarding the patient population in need of a compounded drug as part of the prescriber determination of clinical difference, and that both a hospital and practitioner should produce statements of clinical difference.

FDA Response to Issue Three: FDA's draft guidance states that when an outsourcing facility intends to rely on a prescriber determination to establish that a compounded drug is not essentially a copy of an approved drug, the outsourcing facility should ensure that the determination is documented on the prescription or order for the compounded drug. This means the determination is referenced in the statute at section 503B(d)(2), which FDA cannot change through guidance. FDA cannot give exhaustive guidance regarding what such documentation may contain, but we did provide appropriate examples. Under the guidance, both a prescribing practitioner and a person able to make a representation for the practitioner, such as, potentially, a hospital pharmacy manager, would be able to produce a statement of clinical difference.

Issue Four: At least one commenter asked about the acceptability of specific means of applying a determination statement to a product order.

FDA Response to Issue Four: FDA does not believe a particular format is needed for a prescriber determination of clinical difference, provided that the determination clearly identifies the relevant change made to the compounded product and the clinical difference that the change will produce for patient(s), as determined by the prescriber.

As none of the comments suggested that we revise our estimated burden for the information collection, we have retained our original estimate as follows:

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

Type of reporting recommendations in guidance	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Consultation between the outsourcing facility and prescriber or health care facility, and the notation on the prescription or order documenting the prescriber's determination of clinical difference.	40	100	4,000	0.05 (3 minutes)	200
Checking FDA's drug shortage list and documenting on the prescription that the drug is in shortage.	30	100	3,000	0.03 (2 minutes)	100

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

We estimate that annually a total of approximately 40 outsourcing facilities (''number of respondents'' in table 1, line 1) will consult a prescriber to determine whether he or she has made a determination that the compounded drug has a change that produces a clinical difference for an individual patient as compared to the comparable approved drug and that outsourcing facilities will document this determination on approximately 4,000 prescriptions or orders for compounded drugs (''total annual disclosures'' in table 1, line 1). We estimate that the consultation between the outsourcing facility and the prescriber or health care facility contact adding a notation to each prescription or order that does not already document this determination will take approximately 3 minutes per prescription or order.

We estimate that a total of approximately 30 outsourcing facilities (''number of respondents'' in table 1, line 2) will document this information on approximately 3,000 prescriptions or orders for compounded drugs (''total annual disclosures'' in table 1, line 2). We estimate that checking FDA's drug shortage list and documenting this information will take approximately 2 minutes per prescription or order.

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06169 Filed 3–27–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6397]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling; Calorie Labeling of Articles of Food in Vending Machines and Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget