

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 <sup>1</sup>

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

<sup>1</sup> 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.*

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**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:**

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**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 <sup>1</sup>

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

<sup>1</sup> 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.*

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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