In the **Federal Register** of July 11, 2016 (81 FR 44881), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on October 11, 2016. FDA received approximately 88 comments on the draft guidance. In response to received comments or on its own initiative, FDA made several changes. For example, in response to requests in comments for direction on records retention, FDA added a recommendation that compounders maintain the records described in the guidance for a period of at least 3 years. In addition, to address questions raised in comments, FDA clarified that the policies in this guidance apply to a compounded drug product without regard to the source(s) of the active pharmaceutical ingredient (API) in that product, for example, the policies would apply regardless of whether the compounder used an API that was purchased as an isolate, or if the compounder modified a finished drug product containing an API.

FDA received comments on the draft guidance from hospital organizations regarding the potential implications of the proposed policies in the draft guidance for the preparation of compounded drugs used in in-patient settings. The final guidance notes that FDA is considering the applicability of the policies described in this guidance to hospitals and health systems. We recognize that this issue is of interest to many stakeholders and will convey our further thinking on the applicability of these policies to hospitals and health systems publicly with an opportunity for comment.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on ''Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' 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 guidance contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520). Under the PRA, Federal Agencies must obtain approval from 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 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 before submitting the collection to OMB for approval. To comply with this requirement, in the **Federal Register** of July 11, 2016, we gave interested persons 60 days to comment on the information collection provisions in the draft guidance (81 FR 44881).

The information collection provisions in this guidance have been submitted to OMB for review as required by section 3507(d) of the PRA. These provisions are not in effect until they display a currently valid OMB control number. FDA will publish a notice in the **Federal Register** announcing OMB's decision regarding the information collection provisions in this guidance.

III. Electronic Access

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

Dated: January 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00915 Filed 1–18–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1309]

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 a Commercially Available Drug Product Under Section 503A 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 February 20, 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 a Commercially Available Drug Product Under Section 503A 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.

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

OMB Control Number 0910—NEW

This information collection supports the above captioned Agency guidance document. In the **Federal Register** of July 11, 2016 (81 FR 44881), FDA announced the availability of a draft guidance for industry entitled ''Guidance for Industry on Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act,'' and included an analysis of the associated information collection.

Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes conditions that must be met in order for compounded drugs to receive exemptions from certain sections of the FD&C Act, including section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs); section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with

adequate directions for use) and section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications or abbreviated new drug applications).

One condition of section 503A is that a compounder ''does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product'' (section 503A(b)(1)(D)). However, for the purposes of this section, ''essentially a copy of a commercially available drug product'' does not include a drug product ''in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product'' (section 503A(b)(2)).

The draft guidance states that if a compounder intends to rely on such a determination to establish that a compounded drug is not essentially a copy of a commercially available drug product, the compounder should ensure that the determination is documented on a prescription. If a prescription does not make clear that the prescriber made the determination required by section 503A(b)(2), or a compounded drug is substituted for the commercially available product at the pharmacy, the compounder may contact the prescriber and if the prescriber confirms it, make a notation on the prescription that the compounded product contains a change that makes a significant difference for the patient. The notations should be as specific as those described in this document, and the date of the conversation with the prescriber should be included on the prescription.

In addition, if the drug was compounded because the approved product was not commercially available because it was on the FDA drug shortage list, the prescription or a notation on the prescription should note that it was on the drug shortage list and the date the list was checked.

Finally, compounders under section 503A should maintain records of the frequency in which they have compounded drug products that are essentially copies of commercially available drug products and the number of prescriptions that they have filled for compounded drug products that are essentially copies of commercially available drug products to document that such compounding has not been done ''regularly'' or in ''inordinate amounts.''

FDA received 88 comments on the draft guidance, several of which raised issues pertaining to the information collection provisions in the draft guidance. The issues raised are addressed below.

Issue One: One commenter proposed that any compounded drug with the same Active Pharmaceutical Ingredient (API) as a commercially available drug product should be considered to be ''essentially a copy'' of the commercially available drug product.

FDA Response to Issue One: FDA has not made this proposed change. A compounded drug with the same API as a commercially available drug product may be very different from that commercially available drug product. For example, it may have a different route of administration and a substantially different strength. In such cases, a prescriber determination is not needed because the compounded drug would not be considered to be ''essentially a copy'' of the commercially available drug product, even if it had the same API.

Issue Two: Several individuals submitted comments requesting the collection of additional information than what was proposed in the draft guidance.

- One commenter requested that the medical record maintained by the prescriber should include additional scientific rationale for prescribing the compounded product.
- Another commenter requested documentation to justify the use of a bulk drug substance to compound a product that could have been made starting with FDA-approved products.

FDA Response to Issue Two: Regarding the first comment, this recommendation regarding what information a prescriber should maintain is outside the scope of this guidance. Regarding the second comment, the proposal is beyond the scope of the current guidance and we express no opinion on the proposed analysis and documentation.

Issue Three: Several individuals submitted comments regarding collection of the prescriber determination in the hospital setting.

- Some commenters noted the prescriber determination is not necessary in the hospital setting because pharmacists often determine when a compounded drug is needed for a patient and not the prescriber. For example, one commenter noted that hospitals may have standing policies that specify use of compounded drugs in certain scenarios.
- Other commenters suggested use of a template or ''blanket'' prescriber determination statement when certain drugs are needed for a patient population on a consistent basis.
- Another commenter noted that State scope of practice acts or hospital policy may prohibit pharmacists from writing in the patient chart or altering the electronic health record.

FDA Response to Issue Three: FDA is considering the applicability of the policies described in this guidance to hospitals and health systems and intends to address these issues in separate guidance.

Issue Four: Several individuals commented that it would be burdensome to document the prescriber determination, as well as to call a prescriber to document a prescriber determination when such determination is not evident on the original prescription. Individuals felt a prescriber determination should not be necessary in certain cases, such as when a prescription indicates a compounded drug.

FDA Response to Issue Four: Section 503A(b)(2) provides that a compounded drug is not essentially a copy of a commercially available drug product if there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug. If a prescription already documents the prescriber's determination of significant difference, there is no additional documentation burden for the compounder. However, if a prescription does not make clear that the prescriber made the determination required by section 503A(d)(2), or a compounded drug is substituted for the commercially available product at the pharmacy, the compounder may contact the prescriber, and if the prescriber confirms it, make a notation on the prescription that the compounded product contains a change that makes a significant difference for the patient. 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 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 recordkeeping by health care professionals and health care facilities. Finally, FDA notes that calling a prescriber to document a prescriber determination of significant difference is not a requirement. For example, the

compounder has the option of not filling a prescription with a compounded drug if a prescriber determination is not provided.

Issue Five: One commenter stated that requiring a notation on the prescription that a compounded drug was on the drug shortage list when compounded, and the date the list was checked, would be overly burdensome.

FDA Response to Issue Five: FDA does not believe this presents a significant burden, as a compounder that wants to rely on a drug shortage to establish that a compounded drug is not essentially a copy of a commercially available drug would need to check FDA's shortage website. Noting the date the list was checked is not onerous, and is necessary for FDA to verify compliance during inspections. FDA estimates this activity would take 2 minutes.

Issue Six: One commenter requested clarity on how long records should be maintained; what specific information should be maintained; and when such records should be presented to FDA.

FDA Response to Issue Six: FDA has revised the guidance to include a recommended duration of 3 years for maintaining records. The guidance describes the records that can be retained to demonstrate compliance. FDA may request to review such records during establishment inspections.

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

We estimate that annually a total of approximately 6,888 compounders (''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 significant difference for a patient as compared to the comparable commercially available drug, and that the compounders will document this determination on approximately 172,200 prescription orders for compounded drugs (''total annual disclosures'' in table 1, line 1). We estimate that the consultation between the compounder and the prescriber and adding a notation to each prescription that does not already document this determination will take approximately 3 minutes per prescription order.

In addition, we estimate that a total of approximately 6,888 compounders (''number of respondents'' in table 1, line 2) will document this information on approximately 344,400 prescription 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 order.

We estimate that a total of approximately 3,444 compounders (''number of recordkeepers'' in table 2) will keep approximately 165,312 records (''total annual records''). We estimate that maintaining the records will take approximately 2 minutes per record.

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 compounder and prescriber and the notation on the prescription documenting the prescriber's determination of significant difference.	6,888	50	344,400	0.05 (3 minutes)	17,220
Checking FDA's drug shortage list and documenting on the prescription that the drug is in shortage.	6,888	50	344,400	0.03 (2 minutes)	10,332
Total	.....	.....	.....	.....	27,552

[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 recordkeeping	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records of frequency and number of prescriptions filled for compounded drugs that are essentially a copy.	3,444	48	165,312	0.03 (2 minutes)	4,959

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

Dated: January 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00917 Filed 1–18–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0055]

Gastrointestinal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Gastrointestinal Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing