comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: June 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15372 Filed 7–1–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0779]

Draft Guidance for Industry on Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under the Federal Food, Drug and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act.'' This draft guidance describes FDA's current expectations regarding compliance with current good manufacturing practice (CGMP) requirements for facilities that compound human drugs and register with FDA as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), in accordance with provisions added by the Drug Quality and Security Act (DQSA). FDA is also soliciting public input on specific potential alternative approaches regarding certain CGMP requirements. These potential approaches are explained in detail in the draft guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 2, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian Hasselbalch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4364, Silver Spring, MD 20993–0002, 301–796–3279.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Current Good Manufacturing Practice-Interim Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act.'' On November 27, 2013, President Obama signed the DQSA (Public Law 113–54), which added section 503B to the FD&C Act (21 U.S.C. 353b). Under section 503B(b) of the FD&C Act, a compounder can register as an outsourcing facility with FDA. Drug products compounded in a registered outsourcing facility can qualify for exemptions from the FDA approval requirements in section 505 of the FD&C Act (21 U.S.C. 355) and the requirement to label products with adequate directions for use under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) if the requirements in section 503B are met. Outsourcing facilities will be inspected by FDA and must comply with other provisions of the FD&C Act, including CGMP requirements under section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)).

Under section 501(a)(2)(B) of the FD&C Act, a drug is deemed to be adulterated if it is not produced in accordance with CGMP. FDA's regulations regarding CGMP requirements for the preparation of drug products have been established in 21 CFR parts 210 and 211. FDA intends to issue more specific CGMP regulations for outsourcing facilities. Until final regulations are issued, this draft guidance describes FDA's expectations regarding outsourcing facilities and the CGMP requirements in parts 210 and 211 during this interim period. This draft guidance reflects FDA's intent to recognize the differences between compounding outsourcing facilities and conventional drug manufacturers, and to tailor CGMP requirements to the nature of the specific compounding operations conducted by outsourcing facilities while maintaining the minimum standards necessary to protect patients from the risks of contaminated or otherwise substandard compounded drug products. This draft guidance is only applicable to drugs compounded in accordance with section 503B of the FD&C Act.

FDA intends to focus its inspectional and enforcement efforts on those aspects of compounding operations that pose the highest risk to patient safety. In particular, the primary focus of this draft guidance is on those aspects of part 211 that relate to sterility assurance of sterile drug products and the safety of compounded drug products more generally, with respect to strength (e.g., subpotency, superpotency), and labeling or drug product mix-ups.

II. Specific Request for Comments and Information

In addition to comments on the draft guidance generally, FDA is requesting comments and related supporting information on the following specific issues: (1) alternative approaches that would enable an outsourcing facility to have confidence in the quality of incoming components from sources used by multiple outsourcing facilities without each individual outsourcing facility having to conduct periodic laboratory testing to confirm the information in the third-party supplier's certificate of analysis and (2) alternative approaches that would minimize the need for outsourcing facilities to establish an in-house laboratory while providing confidence about the accuracy of testing performed by a third party used by more than one outsourcing facility. FDA has described these potential alternative approaches in the draft guidance and is seeking public comment on these and any other alternative approaches.

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 Agency's current thinking on ''Current Good Manufacturing Practice-Interim Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit electronic comments regarding this document to *http://www.regulations.gov,* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection are given under this section with an estimate of the annual recordkeeping, third-party disclosure, and reporting burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

We invite 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.

Title: Guidance for Industry, Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act.

Description: The draft guidance describes FDA's expectations regarding compliance with CGMP requirements for facilities that register with FDA as outsourcing facilities under section 503B of the FD&C Act. The primary focus of the draft guidance is on sterility assurance of sterile products and the safety of compounded drug products with respect to strength (e.g., subpotency, superpotency), and labeling or drug product mix-ups. OMB has already approved the information collection (recordkeeping) contained in FDA's CGMP regulations in part 211 (OMB control number 0910–0139). FDA believes that much of the recordkeeping burden that would result from the draft guidance is already incurred by outsourcing facilities in the normal course of their business activities. Thus, the burden estimates for these ''usual and customary'' business practices are not included in the calculation of burden that follows (see 5 CFR 1320.3(b)(2).

The draft guidance contains the following collections of information under the PRA:

1. Facility Design

The draft guidance describes those elements of facility design of outsourcing facilities that are considered critical to assuring the quality of compounded sterile drug products at those facilities. For example, the draft guidance states that sterile drugs should be produced only in ISO 5 or better air quality, and that the ISO 5 zone or critical area must be qualified (i.e., shown to meet the specifications). In section III.A, the draft guidance lists certain studies and tests which should be successfully performed for outsourcing facilities, and states that the results of these studies and tests should be documented.

We estimate that annually a total of approximately 50 outsourcing facilities [1] (''No. of Recordkeepers'' in table 1, row 1) will individually document approximately 20 studies and tests (''Total Annual Records'' in table 1, row 1) that are critical to assuring the quality of compounded sterile drug products. We also estimate that preparing and maintaining each record as described in the draft guidance will take on average approximately 1.5 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 1).

2. Control Systems and Procedures for Maintaining Suitable Facilities

The draft guidance describes certain controls, procedures, and documentation that should be established and followed for maintaining suitable facilities and to prevent contamination and mix-ups during the course of aseptic operations at outsourcing facilities. Procedures must be established that assign responsibility for and describe cleaning schedules, methods, equipment, and materials. In addition, the guidance describes that procedures should ensure recording of instances when there is a loss of positive pressure in the clean room during production.

We estimate that annually a total of approximately 50 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 2) will individually establish and maintain approximately 3 records (procedures and documentation) for maintaining suitable outsourcing facilities (''Total Annual Records'' in table 1, row 2). We also estimate that preparing and maintaining each record as described in section III.B of the draft guidance will take on average approximately 5 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 2).

3. Environmental and Personnel Monitoring

Under the draft guidance, procedures for environmental and personnel monitoring in the aseptic processing area for viable, nonviable, and total particulate matter should be established and followed in outsourcing facilities. The procedures should include establishing the validity of the microbiological media, including the preparation, sterilization, and growth potential of the media used in performing tests.

We estimate that annually a total of approximately 50 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 3) will individually establish approximately 1,200 environmental and personnel monitoring procedures and records to document test results (''Total Annual Records'' in table 1, row 3) for the aseptic processing areas. We also estimate that preparing and maintaining the environmental and personnel monitoring procedures as described in section III.C of the draft guidance will take on average approximately 0.25

[1] This is an estimate of the number of facilities that will register as outsourcing facilities in fiscal year 2014 (which runs from October 1, 2013 to September 30, 2014). As of April 30, 2014, 40 facilities had registered as outsourcing facilities, and on average, 2 facilities have registered each month for the past 3 months, but these estimates are highly uncertain. Annual establishment fees will be assessed for each outsourcing facility registered on or after October 1, 2014. It is unknown how many facilities will remain as registered outsourcing facilities once these fees take effect.

hours for each record (''Average Burden per Recordkeeping'' in table 1, row 3).

4. Equipment, Containers, and Closures

Procedures and documentation should be established and maintained for testing compounding equipment and containers and closures to ensure the quality of compounded drug products at outsourcing facilities.

We estimate that annually a total of approximately 50 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 4) will individually establish and maintain approximately 1,000 procedures and documentation for testing equipment, containers, and closures (''Total Annual Records'' in table 1, row 4) in the aseptic processing areas. We also estimate that preparing and maintaining these procedures and documentation as described in section III.D of the draft guidance will take on average approximately 0.25 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 4).

5. Components

Procedures should be established and records maintained concerning the source and quality of components such as raw materials or ingredients used in producing compounded sterile drug products at outsourcing facilities.

We estimate that annually a total of approximately 50 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 5) will individually establish and maintain approximately 240 records of testing to ensure the quality of components used in producing compounded drugs, as recommended in section III.E of the draft guidance (''Total Annual Records'' in table 1, row 5). We also estimate that preparing and maintaining these records will take on average approximately 4 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 5).

6. Production and Process Controls

Production and process documentation and procedures, such as batch records, must be established to assure the quality of compounded sterile drug products at outsourcing facilities. Training on aseptic technique, cleanroom behavior, gowning, and procedures covering aseptic manufacturing area operations must be established. Sterilization validation of operations (e.g., holding vessels, filling equipment, lyophilizer) and periodic verification activities and results must be documented.

We estimate that annually a total of approximately 50 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 6) will individually establish and maintain approximately 5,000 records pertaining to production and process controls, such as validation procedures and training, to assure the quality of compounded sterile drug products (''Total Annual Records'' in table 1, row 6). We also estimate that preparing and maintaining these records, as described in section III.F of the draft guidance, will take on average approximately 0.25 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 6).

7. Release Testing

Compounded drug products produced at outsourcing facilities must be tested to determine whether they meet final product specifications prior to release for distribution, and procedures for final release testing must be established and followed.

We estimate that annually a total of approximately 50 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 7) will individually establish and maintain approximately 240 records pertaining to final release testing of compounded drug products, including release testing procedures and documentation (''Total Annual Records'' in table 1, row 7). We also estimate that preparing and maintaining these records, as described in section III.G of the draft guidance, will take on average approximately 4 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 7).

If sterility testing is not completed prior to release under certain conditions described in section III.G of the draft guidance, procedures must be established that specify that if the product fails to meet a criterion for sterility, all healthcare and other facilities that received the product must be immediately notified of the test results and provided with any appropriate information and recommendations to aid in the treatment of patients; the notification must be documented; and FDA must be notified in writing.

We estimate that annually a total of approximately 10 outsourcing facilities (''No. of Respondents'' in table 2, row 1) will individually send approximately 1 notification of test results to all healthcare and other facilities that received the compounded drug product and provide them with any appropriate information and recommendations to aid in the treatment of patients (''Total Annual Disclosures'' in table 2, row 1). We also estimate that preparing and sending each notification will take approximately 5 hours (''Average Burden per Disclosure'' in table 2, row 1).

We also estimate that annually, a total of approximately 10 outsourcing facilities (''No. of Respondents'' in table 3) will individually submit to FDA 1 notification of the test results for any compounded drug product that fails to meet a sterility criterion (''Total Annual Responses'' in table 3). Preparing and submitting this information will take approximately 5 hours per notification (''Average Burden per Response'' in table 3).

8. Laboratory Controls

Each laboratory used to conduct testing of components, in-process materials, and finished drug products for outsourcing facilities must follow written procedures for the conduct of each test and document the results, establish sampling and testing procedures to ensure that components, in-process materials, and drug products conform to the product specifications, and keep complete records of all tests performed to ensure compliance with established specifications and standards, including examinations and assays.

We estimate that annually a total of approximately 50 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 8) will individually establish and maintain approximately 1,000 laboratory records as described in section III.H of the draft guidance (''Total Annual Records'' in table 1, row 8). We also estimate that preparing and maintaining these records will take on average approximately 0.5 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 8).

9. Stability/Expiration Dating

Stability testing is used to ensure that a drug product will retain its quality (in particular, strength) and remain sterile through the labeled expiration date. The draft guidance recommends that procedures established by outsourcing facilities for assessing the stability of drug products should include: (1) using stability-indicating test methods that are reliable, meaningful and specific; (2) evaluating samples of the drug product in the same container closure system in which the drug product will be marketed; (3) evaluating samples for stability that are representative of the lot or batch from which they were obtained and are stored under suitable conditions; and (4) testing to evaluate antimicrobial effectiveness (resistance to antimicrobial contamination) for drug products labeled or intended to be multiple dose.

We estimate that annually a total of approximately 50 outsourcing facilities (''No. of Recordkeepers'' in table 1, row

9) will individually establish and maintain approximately 90 procedures for stability studies to determine an expiration date (''Total Annual Records'' in table 1, row 9) for compounded drug products. We also estimate that preparing and maintaining these procedures as described in section III.I of the draft guidance will take approximately 5 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 9).

10. Packaging and Labels

Packaging of sterile drugs must ensure the sterility and integrity of the product until it is administered to a patient, and product labels must contain required information and labeling operations must include controls to prevent mix-ups. Procedures should be established by outsourcing facilities for packaging and labeling operations for compounded sterile drug products, including the following: (1) The container, closure, and packaging systems should provide adequate protection against foreseeable external factors in storage, shipment, and use that can cause contamination or deterioration; (2) packaging records should include specimens of all labels used; procedures should be established for issuance of labels, examination of issued labels, reconciliation of used labels to prevent mix-ups; (3) there should be physical/spatial separation between different labeling and packaging operations to prevent mix-ups; and (4) controls should be established that assure proper identification of any filled containers of sterile products that are stored unlabeled for any period of time.

We estimate that annually a total of approximately 50 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 10) will individually establish and maintain approximately 20 procedures and records for packaging operations and labels (''Total Annual Records'' in table 1, row 10) for compounded drug products. We also estimate that preparing and maintaining these procedures and records as described in section III.J of the draft guidance will take approximately 5.5 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 10).

11. Quality Assurance Activities

A quality control unit must be established by outsourcing facilities to oversee various aspects of compounded sterile drug production and to monitor quality assurance. The responsibilities of the quality control unit must be established in procedures and should include investigations and development and oversight of appropriate corrective actions and preventive actions regarding: Rejected lots of finished product, unexpected results or trends, validation and stability failures, and process deviations or equipment malfunctions that involve critical equipment. The quality control unit also is responsible for ensuring that sampling and testing are conducted to ensure that appropriate specifications are met, and for product complaint handling.

We estimate that annually a total of approximately 50 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 11) will individually establish approximately 8 procedures on the responsibilities of the quality control unit (''Total Annual Records'' in table 1, row 10) as described in section III.K of the draft guidance. We also estimate that preparing and maintaining these procedures will take approximately 3 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 11).

The total estimated recordkeeping, third party disclosure, and reporting burdens for the draft guidance are as follows:

TABLE 1—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
Facility Design	50	20	1,000	1.5	1,500
Control Systems and Procedures For Maintaining Suitable Facilities.	50	3	150	5	750
Environmental and Personnel Monitoring.	50	1,200	60,000	0.25 (15 minutes)	15,000
Equipment, Containers, and Closures.	50	1,000	50,000	0.25 (15 minutes)	12,500
Components	50	240	12,000	4	48,000
Production and Process Controls	50	5,000	250,000	0.25 (15 minutes)	62,500
Release Testing	50	240	12,000	4	48,000
Laboratory Controls	50	1,000	50,000	0.5 (30 minutes)	25,000
Stability/Expiration Dating	50	90	4,500	5	22,500
Packaging and Labels	50	20	1,000	5.5	5,500
Quality Assurance Activities	50	8	400	3	1,200
Total	50	8,821	441,050		242,450

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of disclosure & proposed 21 CFR section	Number of respondents	Frequency per disclosure	Total annual disclosures	Average burden per disclosure	Total hours
Notification that a compounded drug product fails to meet a sterility criterion.	10	1	10	5	50
An expiration date is added to the compounded drug product's label.	50	540	27,000	0.25 (15 minutes)	6,750
Total	6,800				

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

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of reporting & proposed 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification to FDA that a compounded drug product fails to meet a sterility criterion	10	1	10	5	50

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

V. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: June 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15370 Filed 7–1–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1525]

Bulk Drug Substances That May Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act; Revised Request for Nominations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; revised request for nominations.

SUMMARY: The Food and Drug Administration (FDA or Agency) is preparing to develop a list of bulk drug substances (active ingredients) that may be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), although they are neither the subject of a United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drugs. In response to a notice published in the **Federal Register** of December 4, 2013, interested groups and individuals previously nominated a wide variety of substances for this list. However, many of those nominations either were for a substance that is already the subject of a USP monograph or a component of an FDA-approved drug, were not for bulk drug substances used in compounding as active ingredients, or did not include sufficient information to justify inclusion of the nominated substance on the list. To improve the efficiency of the process for developing the list of bulk drug substances that may be used to compound drug products under section 503A, FDA is providing more detailed information on what it needs to evaluate a nomination. Because the deadline for nominations has passed, FDA is reopening the nomination process so that interested persons can submit nominations of bulk drug substances that are not the subject of a USP or NF monograph or a component of an FDA-approved drug. Interested persons will also have the opportunity to provide adequate support to justify placement of the substances on the list. Bulk drug substances that were previously nominated will not be further considered unless they are renominated and those nominations are adequately supported. Substances that are already eligible for use in compounding or that are not adequately supported will not be placed on the list.

DATES: Submit written or electronic nominations for the bulk drug substances list by September 30, 2014.

ADDRESSES: You may submit nominations, identified by Docket No. FDA–2013–N–1525, by any of the following methods.

Electronic Submissions

Submit electronic nominations in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting ''comments.''

Written Submissions

Submit written nominations in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–1525 for this request for nominations. All nominations received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting nominations, see the ''Request for Nominations'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or nominations received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Emily Helms Williams, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 301–796–3381.

SUPPLEMENTARY INFORMATION:

I. Background

Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions under which a compounded drug product may be entitled to an exemption from certain sections of the FD&C Act. Those conditions include that the licensed pharmacist or licensed physician compounds the drug product using bulk drug substances that (1) comply with the standards of an applicable USP or NF monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A. See section 503A(b)(1)(A)(i) of the FD&C Act. Under section 503A(c)(2), the criteria for determining which substances should appear on the 503A bulk drugs list ''shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.''

Section 503A refers to the definition of ''bulk drug substance'' in FDA regulations at § 207.3(a)(4) (21 CFR 207.3(a)(4)). See section 503A(b)(1)(A) of the FD&C Act. As defined in