4. *Healthcare Safety and Quality Improvement Research (HSQR)*
   Date: October 10–11th, 2019 (Open from 7:30 a.m. to 8:00 a.m. on October 10th and closed for remainder of the meeting)
5. *Healthcare Information Technology Research (HITR)*
   Date: October 24th, 2019 (Open from 8:00 a.m. to 8:30 a.m. on October 24th and closed for remainder of the meeting)

Agenda items for these meetings are subject to change as priorities dictate.

Virginia L. Mackay-Smith,

Associate Director, AHRQ.

[FR Doc. 2019–18928 Filed 8–30–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2019–0077]

Draft Guideline for Prevention and Control of Infections in Neonatal Intensive Care Unit Patients: Draft Recommendations for the Prevention and Control of Staphylococcus aureus in Neonatal Intensive Care Unit Patients

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (HHS), announces the opening of a docket to obtain comment on the *Draft Guideline for Prevention and Control of Infections in Neonatal Intensive Care Unit Patients: Draft Recommendations for the Prevention and Control of* Staphylococcus aureus *in Neonatal Intensive Care Unit Patients* (''*Draft Guideline*''). The *Draft Guideline* provides new, evidence-based recommendations specific to the prevention and control of *Staphylococcus aureus* (*S. aureus*), including methicillin-resistant *S. aureus* (MRSA) and methicillin-sensitive *S. aureus* (MSSA), in neonatal intensive care unit (NICU) patients.

DATES: Written comments must be received on or before November 4, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0077, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Attn: Docket No. CDC–2019–0077, HICPAC Secretariat, 1600 Clifton Rd. NE, Mailstop A07, Atlanta, Georgia 30329.

Instructions: Submissions via *http://regulations.gov* are preferred. All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Kendra Cox, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop A–07, Atlanta, Georgia 30329; Telephone: (404) 639–4000.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted in preparation of the final *Guideline for Prevention and Control of Infections in Neonatal Intensive Care Unit Patients* and may revise the final document as appropriate.

Background

The *Draft Guideline,* located in the ''Supporting & Related Material'' tab of the docket, provides new, evidence-based recommendations specific to the prevention and control of *S. aureus,* including MRSA and MSSA, in NICU patients, including active surveillance testing and decolonization.

The *Draft Guideline* is intended for use by infection prevention staff, healthcare epidemiologists, healthcare administrators, nurses, neonatologists, other healthcare providers, and persons responsible for developing, implementing, and evaluating infection prevention and control programs for NICUs. The guideline can also serve as a resource for societies or organizations to develop more detailed implementation guidance for the prevention of infection in NICU patients.

The Healthcare Infection Control Practices Advisory Committee (HICPAC) worked with national partners, academicians, public health professionals, healthcare providers, and other partners to develop this *Draft Guideline.* HICPAC includes representatives from public health, infectious diseases, regulatory and other federal agencies, professional societies, and other stakeholders.

The draft recommendations in this *Draft Guideline* are informed by a systematic review of the best available literature through February 2017 and of relevant references published since February 2017 suggested by subject matter experts. The Appendix, located in the ''Supporting & Related Material'' tab of the docket, contains search strategies, Evidence Tables containing study-level data examined, and GRADE Tables which aggregate the overall strength and direction of the evidence.

This *Draft Guideline* will not be a federal rule or regulation.

Dated: August 28, 2019.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2019–18907 Filed 8–30–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3240]

List of Bulk Drug Substances for Which There is a Clinical Need 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 or Agency) is

developing a list of bulk drug substances (active pharmaceutical ingredients) for which there is a clinical need (the 503B Bulks List). Drug products that outsourcing facilities compound using bulk drug substances on the 503B Bulks List can qualify for certain exemptions from the Federal Food, Drug, and Cosmetic Act (FD&C Act) provided certain conditions are met. This notice identifies nine bulk drug substances that FDA has considered and is proposing not to include on the list: Dipyridamole, ephedrine sulfate, famotidine, hydralazine hydrochloride, methacholine chloride, sodium bicarbonate, sodium tetradecyl sulfate, trypan blue, and vecuronium bromide. Additional bulk drug substances nominated by the public for inclusion on this list are currently under consideration and will be the subject of future notices.

DATES: Submit either electronic or written comments on the notice by November 4, 2019 to ensure that the Agency considers your comment on this notice before it begins work on a notice reflecting the Agency's final decision about whether to include these substances on the 503B Bulks List.

ADDRESSES: You may submit comments at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–3240 for ''List of Bulk Drug Substances For Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Elizabeth Hankla, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5216, Silver Spring, MD 20993, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory and Regulatory Background

Section 503B of the FD&C Act (21 U.S.C. 353b) describes the conditions that must be satisfied for drug products compounded by an outsourcing facility to be exempt from section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)); section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and section 582 (21 U.S.C. 360eee–1) (concerning drug supply chain security requirements).[1]

Drug products compounded under the conditions in section 503B are not exempt from current good manufacturing practice (CGMP) requirements in section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)).[2] Outsourcing facilities are also subject to FDA inspections according to a risk-based schedule, specific adverse event reporting requirements, and other conditions that help to mitigate the risks of the drug products they compound.[3] Outsourcing facilities may or may not obtain prescriptions for identified individual patients and can, therefore, distribute compounded drugs to healthcare practitioners for ''office stock,'' to hold in their offices in advance of patient need.[4]

One of the conditions that must be met for a drug product compounded by an outsourcing facility to qualify for exemptions under section 503B of the FD&C Act is that the outsourcing facility may not compound a drug using a bulk drug substance unless: (1) The bulk drug substance appears on a list established

[1] Section 503B(a) of the FD&C Act.

[2] Compare section 503A(a) of the FD&C Act (exempting drugs compounded in accordance with that section) with section 503B(a) of the FD&C Act (not providing the exemption from CGMP requirements).

[3] Section 503B(b)(4) and (5) of the FD&C Act.

[4] Section 503B(d)(4)(C) of the FD&C Act.

by the Secretary of Health and Human Services identifying bulk drug substances for which there is a clinical need (the 503B Bulks List) or (2) the drug compounded from such bulk drug substances appears on the drug shortage list in effect under section 506E of the FD&C Act (FDA's drug shortage list) (21 U.S.C. 356e) at the time of compounding, distribution, and dispensing.[5]

Section 503B of the FD&C Act directs FDA to establish the 503B Bulks List by: (1) Publishing a notice in the **Federal Register** proposing bulk drug substances to be included on the list, including the rationale for such proposal; (2) providing a period of not less than 60 calendar days for comment on the notice; and (3) publishing a notice in the **Federal Register** designating bulk drug substances for inclusion on the list.[6]

In March 2019, FDA published a notice that identified two bulk drug substances, nicardipine hydrochloride and vasopressin, that were nominated for inclusion on the 503B Bulks List, and that, after consideration, FDA did not include on that list (84 FR 7383). The March 2019 notice stated that additional bulk drug substances were under evaluation, and that additional substances would be the subject of future notices. This notice identifies nine nominated substances that FDA has evaluated and proposes not to include on the 503B Bulks List.

For purposes of section 503B, *bulk drug substance* means an active pharmaceutical ingredient as defined in 21 CFR 207.1.[7] *Active pharmaceutical ingredient* means any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body, but the term does not include intermediates used in the synthesis of the substance.[8] [9]

For further information about drug compounding and the background for the 503B Bulks List, see 83 FR 43877 (August 28, 2018).

II. Methodology for Developing the 503B Bulks List

A. Process for Developing the List

FDA requested nominations for specific bulk drug substances for the Agency to consider for inclusion on the 503B Bulks List in the **Federal Register** of December 4, 2013 (78 FR 72838). FDA reopened the nomination process in the **Federal Register** of July 2, 2014 (79 FR 37750), and provided more detailed information on what FDA needs to evaluate nominations for the list. On October 27, 2015 (80 FR 65770), the Agency opened a new docket, FDA–2015–N–3469, to provide an opportunity for interested persons to submit new nominations of bulk drug substances or to renominate substances with sufficient information.

As FDA evaluates bulk drug substances, it intends to publish notices for public comment in the **Federal Register** that describe the FDA's proposed position on each substance along with the rationale for that position.[10] After considering any comments on FDA's proposals regarding whether to include nominated substances on the 503B Bulks List, FDA intends to consider whether input from the Pharmacy Compounding Advisory Committee (PCAC) on the nominations would be helpful to the Agency in making its determination, and if so, it will seek PCAC input.[11] Depending on its review of the docket comments and other relevant information before the Agency, FDA may finalize its proposed determination without change, or it may finalize a modification to its proposal to reflect new evidence or analysis regarding clinical need. FDA will then publish in the **Federal Register** a list identifying the bulk drug substances for which it has determined there is a clinical need and FDA's rationale in making that final determination. FDA will also publish in the **Federal Register** a list of those substances it considered but found that there is no clinical need to use in compounding and FDA's rationale in making this decision.

FDA intends to maintain a current list of all bulk drug substances it has evaluated on its website, and separately identify bulk drug substances it has placed on the 503B Bulks List and those it has decided not to place on the 503B Bulks List. FDA will only place a bulk drug substance on the 503B Bulks List where it has determined there is a clinical need for outsourcing facilities to compound drug products using the bulk drug substance. If a clinical need to compound drug products using the bulk drug substance has not been demonstrated, based on the information submitted by the nominator and any other information considered by the Agency, FDA will not place a bulk drug substance on the 503B Bulks List.

FDA intends to evaluate the bulk drug substances nominated for the 503B Bulks List on a rolling basis. FDA will evaluate and publish in the **Federal Register** its proposed and final determinations in groups of bulk drug substances until all nominated substances that were sufficiently supported have been evaluated and either placed on the 503B Bulks List or identified as bulk drug substances that were considered but determined not to be appropriate for inclusion on the 503B Bulks List.[12]

B. Analysis of Substances Nominated for the List

As noted above, the 503B Bulks List will include bulk drug substances for which there is a clinical need. The Agency is beginning its evaluation of some of the bulk drug substances that were nominated for inclusion on the 503B Bulks List, proceeding case by case, under the clinical need standard provided by the statute.[13] In applying this standard to develop the proposals in this notice, FDA is interpreting the phrase ''bulk drug substances for which there is a clinical need'' to mean that the 503B Bulks List may include a bulk

[5] Section 503B(a)(2)(A) of the FD&C Act.

[6] Section 503B(a)(2)(A)(i)(I) to (III) of the FD&C Act.

[7] 21 CFR 207.3.

[8] Section 503B(a)(2) of the FD&C Act and 21 CFR 207.1.

[9] Inactive ingredients are not subject to section 503B(a)(2) of the FD&C Act and will not be included in the 503B Bulks List because they are not included within the definition of a bulk drug substance. Pursuant to section 503B(a)(3), inactive ingredients used in compounding must comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph, if a monograph exists.

[10] This is consistent with procedure set forth in section 503B(a)(2)(A)(i) of the FD&C Act. Although the statute only directs FDA to issue a **Federal Register** notice and seek public comment when it proposes to include bulk drug substances on the 503B Bulks List, we intend to seek comment when the Agency has evaluated a nominated substance and proposes either to include or not to include the substance on the list.

[11] Section 503B of the FD&C Act does not require FDA to consult the PCAC before developing a 503B Bulks List.

[12] On January 13, 2017, FDA announced the availability of a revised final guidance for industry that provides additional information regarding FDA's policies for bulk drug substances nominated for the 503B Bulks List pending our review of nominated substances under the ''clinical need'' standard entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' (81 FR 37502); available at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf.*

[13] On March 4, 2019, FDA announced the availability of a final guidance entitled ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' (503B Bulks Evaluation Guidance) (84 FR 7390); available at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM602276.pdf.* This guidance describes FDA policies for developing the 503B Bulks List, including the Agency's interpretation of the phrase ''bulk drug substances for which there is a clinical need,'' as it is used in section 503B of the FD&C Act.

drug substance if: (1) There is a clinical need for an outsourcing facility to compound the drug product and (2) the drug product must be compounded using the bulk drug substance. FDA is not interpreting supply issues, such as backorders, to be within the meaning of ''clinical need'' for compounding with a bulk drug substance. Section 503B separately provides for compounding from bulk drug substances under the exemptions from the FD&C Act discussed above if the drug product compounded from the bulk drug substance is on the FDA drug shortage list at the time of compounding, distribution, and dispensing. Additionally, we are not considering cost of the compounded drug product as compared with an FDA-approved drug product to be within the meaning of ''clinical need.''

The bulk drug substances that we are addressing in this notice are components of FDA-approved drug products, and we therefore began our evaluation by asking the following questions:

1. Is there a basis to conclude, for each FDA-approved product that includes the nominated bulk drug substance, that: (a) An attribute of the FDA-approved drug product makes it medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation and (b) the drug product proposed to be compounded is intended to address that attribute?

2. Is there a basis to conclude that the drug product proposed to be compounded must be produced from a bulk drug substance rather than from an FDA-approved drug product?

The reason for question 1 is that unless an attribute of the FDA-approved drug is medically unsuitable for certain patients, and a drug product compounded using a bulk drug substance that is a component of the approved drug is intended to address that attribute, there is no clinical need to compound a drug product using that bulk drug substance. Rather, such compounding would unnecessarily expose patients to the risks associated with drug products that do not meet the standards applicable to FDA-approved drug products for safety, effectiveness, quality, and labeling and would undermine the drug approval process. The reason for question 2 is that to place a bulk drug substance on the 503B Bulks List, FDA must determine that there is a clinical need for outsourcing facilities to compound a drug product *using the bulk drug substance* rather than starting with an FDA-approved drug product.

If the answer to both of these questions is ''yes,'' there may be a clinical need for outsourcing facilities to compound using the bulk drug substance, and we would analyze the question further.[14] If the answer to either of these questions is ''no,'' we generally would not include the bulk drug substance on the 503B Bulks List, because there would not be a basis to conclude that there may be a clinical need to compound drug products using the bulk drug substance instead of administering or starting with an approved drug product.

III. Substances Proposed for the 503B Bulks List

Because the substances in this notice are components of FDA-approved drug products, we considered whether: (1) There is a basis to conclude that an attribute of each FDA-approved drug product containing the bulk drug substance makes each one medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation, and the drug product proposed to be compounded is intended to address that attribute and (2) whether the drug product proposed to be compounded must be compounded using a bulk drug substance.

The nine bulk drug substances that have been evaluated and that FDA is proposing not to place on the list are as follows: dipyridamole, ephedrine sulfate, famotidine, hydralazine hydrochloride, methacholine chloride, sodium bicarbonate, sodium tetradecyl sulfate, trypan blue, and vecuronium bromide. The reasons for FDA's proposals are included below.

A. Dipyridamole

Dipyridamole has been nominated for inclusion on the 503B Bulks List to compound drug products that are used for thallium myocardial perfusion imaging for the evaluation of coronary artery disease in patients who cannot exercise adequately.[15] The proposed route of administration is intravenous, the proposed dosage form is an injection, and the proposed strength is 1 milligram per milliliter (mg/mL) in a 50 mL and 60 mL syringe. The nominated bulk drug substance is a component of FDA-approved drug products (*e.g.,* ANDAs 074521 and 074939). FDA-approved dipyridamole is available as a 5 mg/mL injection for intravenous administration.[16] [17] Per its labeling, it should be diluted to a final concentration of less than or equal to 2.5 mg/mL.[18]

1. Suitability of FDA-Approved Drug Product

The nomination does not identify an attribute of the FDA-approved drug products that makes them medically unsuitable to treat certain patients and that the proposed compounded drug products are intended to address. Specifically, the nomination does not explain why the 5 mg/mL injection (for dilution) is medically unsuitable for certain patients. Accordingly, with respect to the dipyridamole drug products proposed to be compounded, FDA finds no basis to conclude that an attribute of the FDA-approved product makes it medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation.

2. Whether the Drug Product Must Be Compounded From a Bulk Drug Substance

The nomination does not take the position or provide support for the position that drug products containing dipyridamole must be compounded from bulk drug substances rather than by diluting the approved drug product. FDA finds no basis to conclude that the dipyridamole drug products proposed in the nominations must be compounded using a bulk drug substance rather than the approved drug product.

B. Ephedrine Sulfate

Ephedrine sulfate has been nominated for inclusion on the 503B Bulks List to compound drug products that treat acute bronchospasm, drug induced hypotension due to anesthesia, and nasal congestion.[19] The proposed route of administration is intravenous, the proposed dosage form is a preservative-

[14] FDA's 503B Bulks Evaluation Guidance sets forth four additional factors that the Agency generally intends to consider in such an analysis. Because we did not answer ''yes'' to both of the threshold questions for dipyridamole, ephedrine sulfate, famotidine, hydralazine hydrochloride, methacholine chloride, sodium bicarbonate, sodium tetradecyl sulfate, trypan blue, or vecuronium bromide, we did not consider these four additional factors in this proposal.

[15] See Docket No. FDA–2015–N–3469, document no. FDA–2015–N–3469–0031.

[16] See, *e.g.,* ANDA 074521 labeling available as of the date of this notice at *https://www.accessdata.fda.gov/spl/data/baa2cb6d-2b97-4ad3-a5fc-bad3b8bc6175/baa2cb6d-2b97-4ad3-a5fc-bad3b8bc6175.xml.*

[17] Dipyridamole is also approved as an oral tablet and in combination with aspirin as an extended release capsule.

[18] According to the label for ANDA 074521, dipyridamole injection should be diluted in at least a 1:2 ratio with with sodium chloride injection 0.45%, sodium chloride injection 0.9% or dextrose injection 5% for a total volume of approximately 20 to 50 mL.

[19] See Docket No. FDA–2013–N–1524, document nos. FDA–2013–N–1524–2292 and FDA–2013–N–1524–2298.

free solution, and the proposed strengths are 5 mg/mL and 10 mg/mL.[20] The nominated bulk drug substance is a component of FDA-approved drug products (*e.g.,* NDAs 208943 and 208289). FDA-approved ephedrine sulfate is available as a single-dose, preservative-free 50 mg/mL solution for intravenous administration.[21] [22] Per its labeling, ephedrine sulfate must be diluted before administration to achieve the desired concentration as an intravenous bolus or intravenous infusion. The labeling includes preparation instructions for making a solution containing a final concentration of 5 mg/mL of ephedrine sulfate injection for bolus intravenous administration.

1. Suitability of FDA-Approved Drug Product

The nominations do not identify an attribute of the FDA-approved drug products that make them medically unsuitable to treat certain patients and that the proposed compounded drug products are intended to address. Specifically, the nominations do not explain why the single-dose, preservative-free 50 mg/mL solution (for dilution) is medically unsuitable for certain patients. Accordingly, with respect to the ephedrine sulfate drug products proposed to be compounded, FDA finds no basis to conclude that an attribute of the FDA-approved product makes it medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation.

2. Whether the Drug Product Must Be Compounded From a Bulk Drug Substance

The nominations do not take the position or provide support for the position that drug products containing ephedrine sulfate must be compounded from bulk drug substances rather than by diluting the approved drug product. FDA finds no basis to conclude that the ephedrine sulfate drug products proposed in the nominations must be compounded using a bulk drug substance rather than the approved drug product.

[20] Nominator(s) proposed to compound a preservative-free solution. However, they failed to acknowledge that there is a preservative-free formulation of ephedrine sulfate that is marketed or explain why that formulation would be medically unsuitable for certain patients.

[21] See, *e.g.,* NDA 208943 labeling available as of the date of this notice at *https://www.accessdata.fda.gov/spl/data/6df5e5f1-6375-45ff-9905-f19927e92ee2/6df5e5f1-6375-45ff-9905-f19927e92ee2.xml.*

[22] Per the label for NDA 208943, each mL contains ephedrine sulfate 50 mg in water for injection as a single-dose product.

C. Famotidine

Famotidine has been nominated for inclusion on the 503B Bulks List to compound drug products that treat duodenal ulcer disease, esophagitis, gastrointestinal reflux disease, and gastric ulcer disease, among other conditions.[23] The proposed route of administration is intravenous, the proposed dosage form is a preservative-free solution and a diluted injection solution, and the proposed strengths range from 2 mg/mL to 10 mg/mL.[24] The nominated bulk drug substance is a component of FDA-approved drug products (*e.g.,* ANDAs 078641 and 078642). FDA-approved famotidine is available as a single-dose, preservative-free 10 mg/mL solution for intravenous administration.[25] [26] [27] Per its labeling, famotidine may be diluted to a final concentration of 4 mg/mL or 2 mg/mL for bolus administration.[28]

1. Suitability of FDA-Approved Drug Product

The nominations do not identify an attribute of the FDA-approved drug products that make them medically unsuitable to treat certain patients and that the proposed compounded drug products are intended to address. Specifically, the nominations do not explain why the single-dose, preservative-free 10 mg/mL solution (for dilution) is medically unsuitable for certain patients. Accordingly, with respect to the famotidine drug products proposed to be compounded, FDA finds no basis to conclude that an attribute of the FDA-approved product makes it medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation.

2. Whether the Drug Product Must Be Compounded From a Bulk Drug Substance

The nominations do not take the position or provide support for the position that drug products containing famotidine must be compounded from bulk drug substances rather than by diluting the approved drug product. FDA finds no basis to conclude that the famotidine drug products proposed in the nominations must be compounded using a bulk drug substance rather than the approved drug product.

[23] See Docket No. FDA–2013–N–1524, document nos. FDA–2013–N–1524–2292 and FDA–2013–N–1524–2298.

[24] Nominator(s) proposed to compound a preservative-free solution. However, they failed to acknowledge that there is a preservative-free formulation of famotidine that is marketed or explain why that formulation would be medically unsuitable for certain patients.

[25] See, *e.g.,* ANDAs 079641 and 079641 labeling available as of the date of this notice at *https://www.accessdata.fda.gov/spl/data/99bd2efa-ef75-4daf-ae24-ab574adf1a1e/99bd2efa-ef75-4daf-ae24-ab574adf1a1e.xml.*

[26] Per the label for ANDA 079641, famotine injection is available in a non-preserved single-dose vial.

[27] Famotidine is also approved as an oral tablet and a powder for suspension for oral administration.

[28] According to the label for ANDA 078642, to prepare famotidine intravenous solutions, aseptically dilute 2 mL of famotidine injection, USP (solution containing 10 mg/mL) with 0.9% Sodium Chloride Injection or other compatible intravenous solution (see Stability, Famotidine Injection, USP) to a total volume of either 5 mL or 10 mL and inject over a period of not less than 2 minutes. In addition, to prepare famotidine intravenous infusion solutions, aseptically dilute 2 mL of famotidine injection, USP with 100 mL of 5% dextrose or other compatible solution (see Stability, Famotidine Injection, USP), and infuse over a 15- to 30-minute period.

D. Hydralazine Hydrochloride (HCl)

Hydralazine HCl has been nominated for inclusion on the 503B Bulks List to compound drug products that treat essential hypertension.[29] The proposed routes of administration are intravenous and intramuscular, the proposed dosage form is a preservative-free solution, and the proposed strengths are 0.2 mg/mL and 20 mg/mL.[30] The nominated bulk drug substance is a component of FDA-approved drug products (*e.g.,* ANDAs 204680 and 040730). FDA-approved hydralazine HCl is available as a preservative-free 20 mg/mL solution for intravenous and intramuscular administration.[31] [32] [33]

1. Suitability of FDA-Approved Drug Product

The nominations do not identify an attribute of the FDA-approved drug products that make them medically unsuitable to treat certain patients and that the proposed compounded drug products are intended to address. Specifically, the nominations do not explain why the preservative-free 20 mg/mL solution is medically unsuitable for certain patients. Accordingly, with respect to the hydralazine HCl drug

[29] See Docket No. FDA–2013–N–1524, document nos. FDA–2013–N–1524–2292 and FDA–2013–N–1524–2298.

[30] Nominator(s) proposed to compound a preservative-free solution. However, they failed to acknowledge that there is a preservative-free formulation of hydralazine HCl that is marketed or explain why that formulation would be medically unsuitable for certain patients.

[31] See, *e.g.,* ANDA 204680 labeling available as of the date of this notice at *https://www.accessdata.fda.gov/spl/data/92e234dc-d44e-4e81-b305-4a47b1cfe2c3/92e234dc-d44e-4e81-b305-4a47b1cfe2c3.xml.*

[32] Per the label for ANDA 204680, hydralazine HCl is available in a preservative-free, single-dose vial.

[33] Hydralazine HCl is also approved as an oral tablet, as an oral capsule in combination with hydrochlorothiazide, and as an oral tablet in combination with isosorbide dinitrate.

products proposed to be compounded, FDA finds no basis to conclude that an attribute of the FDA-approved product makes it medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation.

2. Whether the Drug Product Must Be Compounded From a Bulk Drug Substance

The nominations do not take the position or provide support for the position that drug products containing hydralazine HCl must be compounded from bulk drug substances rather than by diluting the approved drug product. FDA finds no basis to conclude that hydralazine HCl drug products proposed in the nominations must be compounded using a bulk drug substance rather than the approved drug product.

E. Methacholine Chloride

Methacholine chloride has been nominated for inclusion on the 503B Bulks List to compound drug products that aid in the diagnosis of bronchial airway hyperactivity.[34] The proposed route of administration is inhalation tapering dose kits, the proposed dosage form is an inhalant, and the proposed strengths are as follows: 8 dilutions (0.125 mg/mL, 0.25 mg/mL, 0.5 mg/mL, 1 mg/mL, 2 mg/mL, 4 mg/mL, 8 mg/mL, 16 mg/mL) and 10 dilutions (0.031 mg/mL, 0.0625 mg/mL, 0.125 mg/mL, 0.25 mg/mL, 0.5 mg/mL, 1 mg/mL, 2 mg/mL, 4 mg/mL, 8 mg/mL, 16 mg/mL). The nominated bulk drug substance is a component of an FDA-approved drug product (NDA 019193). FDA-approved methacholine chloride is available as a 100 mg/vial powder for solution to be administered only by inhalation.[35] Per its labeling, methacholine chloride is reconstituted and diluted to the following concentrations with 0.9% sodium chloride injection or 0.9% sodium chloride injection containing 0.4% phenol (pH 7.0): 0.025 mg/mL, 0.25 mg/mL, 2.5 mg/mL, 10 mg/mL, and 25 mg/mL.

1. Suitability of FDA-Approved Drug Product

The nomination does not identify an attribute of the FDA-approved drug product that makes it medically unsuitable to treat certain patients and that the proposed compounded drug products are intended to address. Specifically, the nomination does not explain why the 100 mg/vial powder for solution (for reconstitution) is medically unsuitable for certain patients. Accordingly, with respect to the methacholine chloride drug products proposed to be compounded, FDA finds no basis to conclude that an attribute of the FDA-approved product makes it medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation.

2. Whether the Drug Product Must Be Compounded From a Bulk Drug Substance

The nomination does not take the position or provide support for the position that drug products containing methacholine chloride must be compounded from bulk drug substances rather than by diluting the approved drug product. FDA finds no basis to conclude that the methacholine chloride drug products proposed in the nominations must be compounded using a bulk drug substance rather than the approved drug product.

F. Sodium Bicarbonate

Sodium bicarbonate has been nominated for inclusion on the 503B Bulks List to compound drug products that treat various conditions, including metabolic acidosis, certain drug intoxications, severe diarrhea, and indigestion.[36] The proposed route of administration is intravenous, the proposed dosage forms are an injectable, preservative-free solution, and injection solutions, and the proposed strengths range from 4.2% to 8.4%, as well as unspecified higher concentrations.[37] The nominated bulk drug substance is a component of FDA-approved drug products (*e.g.,* ANDAs 203449 and 202494). FDA-approved sodium bicarbonate is available as a single-dose, preservative-free 1 milliequivalent (mEq/mL) (8.4%) solution for intravenous administration.[38] [39] [40]

1. Suitability of FDA-Approved Drug Product

The nominations do not identify an attribute of the FDA-approved drug products that make them medically unsuitable to treat certain patients and that the proposed compounded drug products are intended to address. Specifically, the nominations do not explain why the single-dose, preservative-free 1 mEq/mL (8.4%) solution is medically unsuitable for certain patients. A nomination submitted by the Outsourcing Facilities Association states that it may be necessary to compound a product with greater concentration than is commercially available, but the nomination does not identify specific higher concentrations that the nominator proposes to compound or provide any data or information supporting the need for a higher concentration. Accordingly, with respect to the sodium bicarbonate drug products proposed to be compounded, FDA finds no basis to conclude that an attribute of the FDA-approved product makes it medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation.

2. Whether the Drug Product Must Be Compounded From a Bulk Drug Substance

The nominations do not take the position or provide support for the position that the proposed sodium bicarbonate products with concentrations at or below 8.4% (1 mEQ/mL) must be compounded from bulk drug substances rather than by diluting the approved drug product. In light of the analysis in section III.6.a. above, we do not consider whether a bulk drug substance must be used to compound a sodium bicarbonate drug product at concentrations higher than 8.4%. FDA finds no basis to conclude that the sodium bicarbonate drug products proposed in the nominations must be compounded using a bulk drug substance rather than the approved drug product.

G. Sodium Tetradecyl Sulfate

Sodium tetradecyl sulfate has been nominated for inclusion on the 503B Bulks List to compound drug products that treat varicose veins.[41] The proposed route of administration is intravenous, the proposed dosage form is an injection solution, and the proposed strengths range from 0.1% to 3%. The nominated

[34] See Docket No. FDA–2013–N–1524, document no. FDA–2013–N–1524–2292.

[35] See, *e.g.,* NDA 208943 labeling available as of the date of this notice at *https://www.accessdata.fda.gov/spl/data/7f538d73-80e2-4c00-911a-df2637e5a4d1/7f538d73-80e2-4c00-911a-df2637e5a4d1.xml.*

[36] See Docket No. FDA–2013–N–1524, document nos. FDA–2013–N–1524–2292 and FDA–2013–N–1524–2298. Also, see Docket No. FDA–2015–N–3469, document no. FDA–2015–N–3469–0095.

[37] Nominator(s) proposed to compound a preservative-free solution. However, they failed to acknowledge that there is a preservative-free formulation of sodium bicarbonate that is marketed or explain why that formulation would be medically unsuitable for certain patients.

[38] See, *e.g.,* ANDA 203449 labeling available as of the date of this notice at *https://www.accessdata.fda.gov/spl/data/0e955d36-928c-4f09-9b34-0cc954e5b1f4/0e955d36-928c-4f09-9b34-0cc954e5b1f4.xml.*

[39] Per the label for ANDA 203449, the solutions contain no bacteriostat, antimicrobial agent, or added buffer and are intended only for use as a single-dose injection.

[40] Sodium bicarbonate is also approved in combination with other ingredients as an injectable, solution for irrigation, and various oral formulations.

[41] See Docket No. FDA–2013–N–1524, document no. FDA–2013–N–1524–2292.

bulk drug substance is a component of an FDA-approved drug product (ANDA 040541). FDA-approved sodium tetradecyl sulfate is available as a 20 mg/2 mL (10 mg/mL; 1%) and 60 mg/2 mL (30 mg/mL; 3%) solution for intravenous administration.[42]

1. Suitability of FDA-Approved Drug Product

The nomination does not identify an attribute of the FDA-approved drug product that makes it medically unsuitable to treat certain patients and that the proposed compounded drug products are intended to address. Specifically, the nomination does not explain why the 20 mg/2 mL (10 mg/mL; 1%) and 60 mg/2 mL (30 mg/mL; 3%) solutions are medically unsuitable for certain patients. Accordingly, with respect to the sodium tetradecyl sulfate drug products proposed to be compounded, FDA finds no basis to conclude that an attribute of the FDA-approved product makes it medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation.

2. Whether the Drug Product Must Be Compounded From a Bulk Drug Substance

The nomination does not take the position or provide support for the position that drug products containing sodium tetradecyl sulfate must be compounded from bulk drug substances rather than by diluting the approved drug product. FDA finds no basis to conclude that the sodium tetradecyl sulfate drug products proposed in the nominations must be compounded using a bulk drug substance rather than the approved drug product.

H. Trypan Blue

Trypan blue has been nominated for inclusion on the 503B Bulks List to compound drug products that aid in staining the eye for cataract surgery and vitrectomy.[43] The proposed route of administration is intraocular,[44] the proposed dosage form is a preservative-free solution, and the proposed strengths are 0.05%, 0.06%, and 0.15%.[45] The nominated bulk drug substance is a component of FDA-approved drug products (*e.g.,* NDAs 021670 and 022278). FDA-approved trypan blue is available as a single-dose, preservative-free 0.06% and 0.15% solution for intraocular administration.[46] [47]

1. Suitability of FDA-Approved Drug Product

The nominations do not identify an attribute of the FDA-approved drug products that make them medically unsuitable to treat certain patients and that the proposed compounded drug products are intended to address. Specifically, the nominations do not explain why the single-dose, preservative-free 0.06% and 0.15% solutions are medically unsuitable for certain patients. Accordingly, with respect to trypan blue drug products proposed to be compounded, FDA finds no basis to conclude that an attribute of the FDA-approved product makes it medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation.

2. Whether the Drug Product Must Be Compounded From a Bulk Drug Substance

The nominations do not take the position or provide support for the position that drug product containing trypan blue must be compounded from bulk drug substances rather than by diluting the approved drug product. FDA finds no basis to conclude that the trypan blue drug products proposed in the nominations must be compounded using a bulk drug substance rather than the approved drug product.

I. Vecuronium Bromide

Vecuronium bromide has been nominated for inclusion on the 503B Bulks List to compound drug products that facilitate endotracheal intubation.[48] The proposed route of administration is rapid intravenous injection or by intravenous infusion using an infusion control device, the proposed dosage form is an injection, and the propose strengths are 10 mg/10 mL (1 mg/mL) in sterile water for injection and 100 mg/100 mL (1 mg/mL) in 0.9% sodium chloride solution. The nominated bulk drug substance is a component of FDA-approved drug products (*e.g.,* ANDAs 079001 and 206670). FDA-approved vecuronium bromide is available as a 10 mg/vial and 20 mg/vial lyophilized powder for solution for intravenous administration (bolus dosing or continuous infusion).[49] Per its labeling, vecuronium bromide is 1 mg/mL after reconstitution with either 10 mL (10 mg/vial) or 20 mL (20 mg/vial) of diluent.[50]

1. Suitability of FDA-Approved Drug Product

The nomination does not identify an attribute of the FDA-approved drug products that make them medically unsuitable to treat certain patients and that the proposed compounded drug products are intended to address. Specifically, the nomination does not explain why the 10 mg/vial and 20 mg/vial lyophilized powders for solution (for reconstitution) are medically unsuitable for certain patients. Accordingly, with respect to the vecuronium bromide drug products proposed to be compounded, FDA finds no basis to conclude that an attribute of the FDA-approved product makes it medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation.

2. Whether the Drug Product Must Be Compounded From a Bulk Drug Substance

The nomination does not take the position or provide support for the position that drug products containing vecuronium bromide must be compounded from bulk drug substances rather than by diluting the approved drug product. FDA finds no basis to conclude that the vecuronium bromide drug products proposed in the

[42] See, *e.g.,* ANDA 040541 labeling available as of the date of this notice at *https://www.accessdata.fda.gov/spl/data/5450f902-fb17-44b8-8c4b-4fefeed1908e/5450f902-fb17-44b8-8c4b-4fefeed1908e.xml.*

[43] See Docket No. FDA–2013–N–1524, document nos. FDA–2013–N–1524–2292 and FDA–2013–N–1524–2298.

[44] One nominator proposed the following route of administration and dosage form: Ophthalmic solution; injection. Thus, FDA determined that the proposed route of administration is intraocular.

[45] Nominator(s) proposed to compound a preservative-free solution. However, they failed to acknowledge that there is a preservative-free formulation of trypan blue that is marketed or explain why that formulation would be medically unsuitable for certain patients.

[46] See, *e.g.,* NDA 021670 labeling available as of the date of this notice at *https://www.accessdata.fda.gov/spl/data/7c57aaf4-e1a1-d191-e053-2a91aa0a757a/7c57aaf4-e1a1-d191-e053-2a91aa0a757a.xml* and NDA 022278 labeling available as of the date of this notice at *https://www.accessdata.fda.gov/spl/data/7c57f83d-da8f-2499-e053-2a91aa0afe8e/7c57f83d-da8f-2499-e053-2a91aa0afe8e.xml.*

[47] Per the label for NDA 021670, each mL contains: 0.6 mg trypan blue, 1.9 mg sodium mono-hydrogen orthophosphate, 0.3 mg sodium di-hydrogen orthophosphate, 8.2 mg sodium chloride, and water for injection. Per the label for NDA 022278, each mL contains: 1.5 mg trypan blue, 1.9 mg sodium mono-hydrogen orthophosphate, 0.3 mg sodium di-hydrogen orthophosphate, 8.2 mg sodium chloride, and water for injection.

[48] See Docket No. FDA–2015–N–3469, document no. FDA–2015–N–3469–0011.

[49] See, *e.g.,* ANDA 079001 labeling available as of the date of this notice at *https://www.accessdata.fda.gov/spl/data/82d6bc45-04a5-409a-9223-da1884b2468f/82d6bc45-04a5-409a-9223-da1884b2468f.xml.*

[50] In addition, the labeling contains infusion rate information for two separate strength solutions: 0.1 mg/mL (10 mg of vecuronium bromide in 100 mL solution) and 0.2 mg/mL (20 mg of vecuronium bromide in 100 mL solution).

nominations must be compounded using a bulk drug substance rather than the approved drug product.

IV. Other Issues Raised in Nominations

Some of the bulk drug substance nominations included in this notice state that there could be a benefit gained from providing drug products containing each of these bulk drug substances that do not require dilution or reconstitution prior to administration. More broadly, as explained above, when a bulk drug substance is a component of an approved drug, FDA asks whether there is a basis to conclude that an attribute of each approved drug product makes each one medically unsuitable to treat certain patients for their condition, an interpretation that protects patients and the integrity of the drug approval process. The nominations do not show that the approved drug product, when not manufactured in the ready-to-use form, is medically unsuitable for certain patients. Nor do the nominations establish that drug products in the relevant concentrations, including ready-to-use products, cannot be prepared from the approved drug products. Rather, they propose to compound a ready-to-use product from bulk drug substances to seek improved efficiency for prescribers or healthcare providers, or to address the possibility that the approved drug might be mishandled by a medical professional, neither of which falls within the meaning of clinical need to compound a drug product using a bulk drug substance.

Some of the nominations for the substances in this notice include statements that these substances should be added to the 503B Bulks List because compounding from the bulk drug substance could help outsourcing facilities address drug shortages and supply disruptions of approved drugs. As noted above, section 503B of the FD&C Act contains a separate provision for compounding from bulk drug substances to address a drug shortage, and we do not interpret the other price- and supply-related issues advanced by the nominations to be within the meaning of ''clinical need'' for compounding with a bulk drug substance.[51]

Some of the nominations for the substances in this notice assert that it would be preferable to compound a drug product using a bulk drug substance rather than using an approved drug product; however, they do not take the position or provide support for the position that a bulk drug substance must be used to prepare these concentrations.[52]

V. Conclusion

For the reasons stated above, we find no basis to conclude that there is a clinical need for outsourcing facilities to compound drug products using the bulk drug substances dipyridamole, ephedrine sulfate, famotidine, hydralazine hydrochloride, methacholine chloride, sodium bicarbonate, sodium tetradecyl sulfate, trypan blue, and vecuronium bromide. We therefore propose to not include dipyridamole, ephedrine sulfate, famotidine, hydralazine hydrochloride, methacholine chloride, sodium bicarbonate, sodium tetradecyl sulfate, trypan blue, and vecuronium bromide on the 503B Bulks List.

Dated: August 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18932 Filed 8–30–19; 8:45 am]

BILLING CODE 4164–01–P

[51] Please see the final guidance entitled ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' (503B Bulks Evaluation Guidance) (84 FR 7390); available at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM602276.pdf* and the **Federal Register** notice entitled ''List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' available at *https://www.federalregister.gov/documents/2019/03/04/2019-03810/list-of-bulk-drug-substances-for-which-there-is-a-clinical-need-under-section-503b-of-the-federal.*

[52] For example, the nominations do not take the position or provide support for the position that a drug product prepared by starting with the approved drug would be unsuitable for administration.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0717]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaigns

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 October 3, 2019.

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 0910–0753. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaigns

OMB Control Number 0910–0753—Extension

Overview of the Evaluation Studies

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors. Section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) supports the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA is currently developing and implementing youth-targeted public education campaigns to help prevent tobacco use among youth and thereby reduce the public health burden of tobacco. The campaigns feature televised advertisements along with complementary ads on radio, on the internet, in print, and through other forms of media.

Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions. Comprehensive evaluation of FDA's