DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Joint Meeting of the Pulmonary-Allergy Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Pulmonary-Allergy Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 10, 2015, from 8 a.m. to 4 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *PADAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committees will discuss the safety of codeine in children 18 years of age and younger. Codeine (most often in combination with acetaminophen) is used for the treatment of pain in children; however, it is contraindicated for the management of pain after tonsillectomy and/or adenoidectomy. Codeine (in combination with other medicines) is used for the relief of cough associated with upper respiratory allergies or the common cold in children.

Codeine is available by prescription and also through the over-the-counter (OTC) Drug Monograph for Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (21 CFR 341.14, 21 CFR 341.74, and 21 CFR 341.90).

The focus of the meeting will be the risk of serious adverse events, such as respiratory depression and death, including reports in children who are CYP2D6 ultra-rapid metabolizers. The committees will discuss whether the use of codeine in children should be restricted further beyond the current contraindication described previously and whether codeine should be available through the OTC Drug Monograph.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person on or before November 24, 2015. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 16, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 17, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Cindy Hong at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27196 Filed 10–26–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3469]

Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503B of the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; establishment of public docket.

SUMMARY: The Food and Drug Administration (FDA or Agency) is developing a list of bulk drug substances (active ingredients) that can be used to compound drug products in accordance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (the 503B bulks list). The Agency previously solicited nominations for the list, but some of the nominated substances were not supported by sufficient information for FDA to evaluate them. FDA is establishing a public docket where these substances can be renominated with sufficient supporting information or to

receive nominations of bulk drug substances that were not previously nominated for consideration for inclusion on the 503B bulks list. Interested parties can also submit comments on nominated substances via this docket.

DATES: Nominations and comments may be submitted to this docket at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2015–N–3469 for ''Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503B of the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments 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: Philantha Bowen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5175, Silver Spring, MD 20993–0002, 301–796–2466.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Drug Quality and Security Act (Pub. L. 113–54), which added a new section 503B to the FD&C Act (21 U.S.C. 353b), outsourcing facilities [1] may qualify for certain exemptions from the FD&C Act if the conditions set forth in the statute are satisfied. Those conditions include that an outsourcing facility does not compound drug products using a bulk drug substance unless the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need (the 503B bulks list), or the drug product compounded from such bulk drug substance appears on the drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) (FDA drug shortage list) at the time of compounding, distribution, and dispensing, and each of the following conditions are met: (1) If an applicable monograph exists under the United States Pharmacopeia (USP), the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substance complies with the monograph; (2) the bulk drug substance is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360); and (3) the bulk drug substance is accompanied by a valid certificate of analysis (see section 503B(a)(2) of the FD&C Act).

Section 503B refers to the definition of ''bulk drug substance'' in FDA regulations at § 207.3(a)(4) (21 CFR 207.3(a)(4)). (See section 503B(a)(2) of the FD&C Act.) As defined in § 207.3(a)(4), a ''bulk drug substance'' is any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

An ''active ingredient'' is any component that 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 of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect. (See § 210.3(b)(7) (21 CFR 210.3(b)(7)).)

[1] ''Outsourcing facilities'' are facilities that meet certain conditions described in section 503B of the FD&C Act, including registering with FDA as an outsourcing facility.

Any component other than an active ingredient is an ''inactive ingredient.'' (See § 210.3(b)(8).) Inactive ingredients used in compounded drug products, which commonly include flavorings, dyes, diluents, or other excipients, need not appear on the Secretary's list of bulk drug substances to be eligible for use in compounding drug products and will not be included on the list.

In a document dated November 27, 2013, published in the **Federal Register** of December 4, 2013 (78 FR 72838), FDA invited all interested persons to nominate bulk drug substances for inclusion on the 503B bulks list. Over 2,000 substances were nominated. However, many of the nominations were not for bulk drug substances used in compounding as active ingredients, or they did not include sufficient information to allow FDA to evaluate the nominated substances for placement on the list. To improve the efficiency of the process for developing the 503B bulks list, FDA reopened the nomination process in July 2014 (79 FR 37747, July 2, 2014), and provided more detailed information on what it needs to evaluate nominations for the list. FDA stated that bulk drug substances that were previously nominated would not be further considered unless they were renominated with adequate support to permit a meaningful evaluation. Substances that were already eligible for use in compounding or that were not adequately supported would not be evaluated for placement on the list.

In response to the July 2, 2014, request for nominations, approximately 2,590 unique substances were nominated. Of the nominated substances, approximately 1,750 are not eligible for inclusion on the list because they are either a finished drug product, a biological product subject to licensure in a biologics license application (BLA), a radiopharmaceutical drug product, a substance with no currently accepted medical use that is included on Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 812(c)), or they appear on the list published by FDA of substances that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective. Of the substances that are not biological products subject to licensure in a BLA, finished drug products, radiopharmaceuticals, do not appear on Schedule I in the CSA, and do not appear on the withdrawn or removed list, approximately 650 substances were nominated with insufficient supporting evidence for FDA to evaluate them.

II. Establishment of a Docket

As described in section III.B of the draft guidance entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act,'' FDA is establishing a public docket so that interested parties can comment on nominated bulk drug substances, nominate bulk drug substances that were not previously nominated for the 503B bulks list, or renominate with adequate supporting information bulk drug substances that were previously nominated but that were not supported by sufficient information for FDA to evaluate them. Docket No. FDA–2013–N–1524 is closed for comment. Therefore, this new docket can be used for commenting on nominations previously submitted to that docket as well as for submitting new nominations.

In the **Federal Register** document seeking nominations, FDA stated that the following information about clinical need is necessary to provide adequate support for nominations to the 503B bulks list:

- A statement describing the medical condition(s) that the drug product to be compounded with the nominated bulk drug substances is intended to treat;
- A list of FDA-approved drug products, if any, that address the same medical condition;
- If there are any FDA-approved drug products that address the same medical condition, an explanation of why a compounded drug product is necessary;
- If the approved drug product is not suitable for a particular patient population, an estimate of the size of the population that would need a compounded drug product;
- A bibliography of safety and efficacy data for the drug product compounded using the nominated substance, if available, including any relevant peer-reviewed medical literature; and
- If there is an FDA-approved drug product that includes the bulk drug substance nominated, an explanation of why the drug product proposed to be compounded must be compounded from bulk rather than with the FDA-approved drug product.

Therefore, to be considered for placement on the 503B bulks list, this information should be submitted for each nominated substance.

Interested groups and individuals may nominate specific bulk drug substances for inclusion on the 503B bulks list, renominate previously nominated substances with additional information, or comment on nominated substances. Nominations will only be evaluated if they are for specific active ingredients that meet the definition of a bulk drug substance in § 207.3(a)(4). Nominated substances that do not meet this definition will not be included on the list. To fully evaluate a bulk drug substance using the criteria identified in this document, FDA needs the following information about both the nominated bulk drug substance and the drug product(s) that will be compounded using such substance:

A. Active Ingredients

1. Confirmation That the Nominated Substance Is a Bulk Drug Substance

- A statement that the nominated substance is an active ingredient that meets the definition of ''bulk drug substance'' in § 207.3(a)(4), and an explanation of why the substance is considered an active ingredient when it is used in compounded drug products, citing specific sources that describe the active properties of the substance.

2. General Background on the Bulk Drug Substance

- Ingredient name;
- chemical name;
- common name(s); and
- identifying codes, as available, from FDA's Unique Ingredient Identifiers (UNII) used in the FDA/USP Substance Registration System, available at *http://fdasis.nlm.nih.gov/srs/*. Because substance names can vary, this code, where available, will be used by the Agency to confirm the exact substance nominated and to identify multiple nominations of the same substance so the information can be reviewed together.
- Chemical grade of the ingredient;
- description of the strength, quality, stability, and purity of the ingredient, and a copy of a certificate of analysis that is representative of the characteristics of the nominated ingredient;
- information about how the ingredient is supplied (*e.g.,* powder, liquid); and
- information about recognition of the substance in foreign pharmacopeias and the status of its registration(s) in other countries, including whether information has been submitted to USP for consideration of monograph development.

B. Clinical Need To Compound

For FDA to be able to meaningfully evaluate a substance, the information provided regarding the clinical need for compounding with a bulk drug substance must be specific to the particular substance nominated and

drug product to be compounded. A ''boilerplate'' or general explanation of clinical need for compounding with bulk drug substances will not enable FDA to conduct an adequate review. Prescribers of the compounded drug products who may be in the best position to explain why there is a clinical need for a compounded drug product may provide data in support of a nomination. The following information about clinical need is necessary to provide adequate support for nominations to the 503B bulks list:

- A statement describing the medical condition(s) that the drug product to be compounded with the nominated bulk drug substances is intended to treat (*i.e.,* what patient need is met by the drug product compounded with the bulk drug substance);
- a list of FDA-approved drug products, if any, that address the same medical condition;
- if there are FDA-approved drug products that address the same medical condition, an explanation of why a compounded drug product is necessary (*i.e.,* why the approved drug product is not suitable for a particular patient population);
- if the approved drug product is not suitable for a particular patient population, an estimate of the size of the population that would need a compounded drug product (*e.g.,* for a drug product compounded from bulk because of patient allergies or other intolerances to excipients in FDA-approved drug products, FDA expects the supporting information to include a good faith estimate of the patient population with the specific medical condition that suffers from the allergy or intolerance, with citations to the literature regarding the incidence of the condition or a statement that a search was conducted and no references were found); [2]
- a bibliography of safety and efficacy data for the drug compounded using the nominated substance,[3] if available, including any relevant peer-reviewed medical literature; and
- if there is an FDA-approved drug product that includes the bulk drug substance nominated, an explanation of why the drug product proposed to be compounded must be compounded from bulk rather than with the FDA-approved drug product.

General or boilerplate statements regarding the need to compound from the bulk drug substance or the benefits of compounding generally will not be considered sufficient. Note that the Agency does not consider supply issues, such as backorders, that do not rise to the level of a drug shortage listed on FDA's drug shortage Web site as evidence of a clinical need for compounding with a bulk drug substance, and section 503B of the FD&C Act already allows compounding from bulk drug substances if the compounded drug product is on the FDA drug shortage list. Similarly, considerations of cost and convenience will not be considered indicators of clinical need.

C. Information on the Drug Product That Will Be Compounded With the Bulk Drug Substance

- Information about the dosage form(s) into which the bulk drug substance will be compounded;
- information about the strength(s) of the compounded drug product(s);
- information about the anticipated route(s) of administration of the compounded drug product(s); and
- information about the previous use(s) of the compounded drug product(s).

D. Process for Submitting Nominations and Comments

Because the prior deadline for submitting nominations has passed, FDA is opening this docket so that interested persons can submit nominations of bulk drug substances and provide adequate support for FDA to evaluate whether those substances should be placed on the 503B bulks list. Bulk drug substances that were previously nominated and for which inadequate information was provided [4] need to be renominated with the information identified in this document to be considered for inclusion on the 503B bulks list. Nominators are encouraged to submit as much of the information identified in this document as possible. Unless adequate supporting data is received for a bulk drug substance, FDA will be unable to consider it further for inclusion on the list.

For efficient consolidation and review of nominations, nominators are encouraged to submit their nominations in an editable Excel file. Specifically, nominators are encouraged to format their nominations as follows:

Column A—What information is requested?	Column B—Put data specific to the nominated substance
What is the name of the nominated ingredient?	Provide the ingredient name.
Is the ingredient an active ingredient that meets the definition of ''bulk drug substance'' in § 207.3(a)(4)?	Provide an explanation for why it is considered an active ingredient when it is used in specific compounded drug products, and provide citations to specific sources that describe its active properties.
What is the chemical name of the substance?	Chemical name.
What is the common name of the substance?	Common name.
Does the substance have a UNII code?	UNII code.
What is the chemical grade of the substance?	Provide the chemical grade.
What is the strength, quality, stability, and purity of the ingredient?	Provide the strength, quality, stability, and purity information and attach a certificate of analysis.
How is the ingredient supplied?	Describe how the ingredient is supplied (e.g., powder, liquid).
Is the substance recognized in foreign pharmacopeias or registered in other countries?	List the foreign pharmacopeias or other countries in which it is registered.
Has information been submitted about the substance to the USP for consideration of monograph development?	Put yes, no, or unknown. If yes, state the status of the monograph, if known.

[2] For example, if there is a need to compound a drug product from bulk drug substances due to patient sensitivity to a preservative or other excipient in the approved drug product, the supporting data is expected to set forth the number of patients for whom the drug product is prescribed that are allergic or sensitive to that particular excipient.

[3] FDA recognizes that the available safety and efficacy data supporting consideration of a bulk drug substance for inclusion on the list may not be of the same type, amount, or quality as is required to support a new drug application. Note that data regarding safety and efficacy, while relevant, is not indicative of a clinical need for a particular bulk drug substance, and additional information regarding the clinical need must be provided.

[4] As referenced in this document, a list of the substances in this category is available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467373.pdf.*

Column A—What information is requested?	Column B—Put data specific to the nominated substance
What medical condition(s) is the drug product compounded with the bulk drug substances intended to treat?	Describe the medical condition(s) that the drug product compounded with the bulk drug substances is intended to treat.
Are there other drug products approved by FDA to treat the same medical condition?	List the other approved treatments.
If there are FDA-approved drug products that address the same medical condition, why is there a clinical need for a compounded drug product?	Provide a justification for clinical need, including an estimate of the size of the population that would need the compounded drug.
Are there safety and efficacy data on compounded drugs using the nominated substance?	Provide a bibliography of safety and efficacy data for the drug compounded using the nominated substance, if available, including any relevant peer-reviewed medical literature.
If there is an FDA-approved drug product that includes the bulk drug substance nominated, is it necessary to compound a drug product from the bulk drug substance rather than from the FDA-approved drug product?	Provide an explanation of why it is necessary to compound from the bulk drug substance.
What dosage form(s) will be compounded using the bulk drug substance?	State the dosage form(s).
What strength(s) will be compounded from the nominated substance?	List the strength(s) of the drug product(s) that will be compounded from the nominated substance, or a range of strengths, if known.
What are the anticipated route(s) of administration of the compounded drug product(s)?	List the route(s) of administration of the compounded drug product(s).
Has the bulk drug substance been used previously to compound drug product(s)?	Describe previous uses of the bulk drug substance in compounding.
Is there any other relevant information?	Provide any other information you would like FDA to consider in evaluating the nomination.

In addition to nominating new substances or renominating substances previously nominated without sufficient supporting information, individuals and organizations will be able to comment via the docket established by this notice on substances nominated for the 503B bulks list that have not yet been addressed in a **Federal Register** document proposing substances for the 503B bulks list. Comments may be submitted regarding nominations submitted to both this docket and nominations previously submitted to Docket No. FDA–2013–N–1524. Comments may provide any relevant information about particular bulk drug substances, including that in support of, or in opposition to, the placement of a nominated bulk drug substance on the 503B bulks list. However, comments submitted should not address the 503B bulks list generally or other matters related to the Agency's regulation of compounding. Comments about nominated substances that have been addressed by the Agency in a **Federal Register** document proposing substances for the 503B bulks list should be submitted to the docket for the document in which the substance is addressed.

Please do not submit comments that have already been submitted to other dockets. Such submissions are duplicative and not helpful to the Agency. If comments on particular documents or issues are submitted to this docket rather than the docket specifically opened for the particular document or issue, the comment might not be considered as the specific documents are being finalized and issues considered. FDA will not respond to questions submitted to this docket.

Information in the docket will be publicly available. Therefore, we remind nominators and commenters not to submit personal or confidential information.

Dated: October 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27270 Filed 10–26–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3455]

Medical Devices; Exemptions From Premarket Notifications; Class II Devices; Autosomal Recessive Carrier Screening Gene Mutation Detection System; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intent to exempt from the premarket notification requirements autosomal recessive carrier screening gene mutation detection systems, subject to certain limitations. These devices are qualitative in vitro molecular diagnostic systems used for genotyping of clinically relevant variants in genomic deoxyribonucleic acid (DNA) isolated from human specimens intended for prescription use or over-the-counter use. These devices are intended for autosomal recessive disease carrier screening in adults of reproductive age. These devices are not intended for copy number variation, cytogenetic, or biochemical testing. FDA is publishing this notice in order to obtain comments regarding the proposed exemption.

DATES: Submit electronic or written comments by November 27, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the