appointing members to the CAC, the Board will consider a number of factors, including diversity in terms of subject matter expertise, geographic representation, and the representation of women and minority groups.

CAC members must be willing and able to make the necessary time commitment to participate in organizational conference calls and prepare for and attend meetings two times per year (usually for two days). The meetings will be held at the Board's offices in Washington, DC. The Board will provide a nominal honorarium and will reimburse CAC members only for their actual travel expenses subject to Board policy.

By order of the Board of Governors of the Federal Reserve System, acting through the Director of the Division of Consumer and Community Affairs under delegated authority, March 26, 2019.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2019–06406 Filed 4–4–19; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2730]

Risk Evaluation and Mitigation Strategy: The Food and Drug Administration's Application of Statutory Factors in Determining When a Risk Evaluation and Mitigation Strategy Is Necessary; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Risk Evaluation and Mitigation Strategy: FDA's Application of Statutory Factors in Determining When a Risk Evaluation and Mitigation Strategy Is Necessary.'' This guidance is intended to clarify how FDA applies the factors set forth in the Federal Food, Drug, and Cosmetic Act (FD&C Act) in determining whether a risk evaluation and mitigation strategy (REMS) is necessary to ensure that the benefits of a drug outweigh its risks. This guidance is one of several developed to fulfill performance goals that FDA agreed to satisfy in the reauthorization of the prescription drug user fee program (the Prescription Drug User Fee Act (PDUFA) V). This guidance finalizes the draft guidance entitled ''FDA's Application of Statutory Factors in Determining When a REMS Is Necessary,'' issued September 21, 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on April 5, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2016–D–2730 for ''REMS: FDA's Application of Statutory Factors in Determining When a REMS Is Necessary.'' 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Jason Bunting, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6366, Silver Spring, MD 20993, 301–796–1292, *Jason.Bunting@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, *Stephen.Ripley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''REMS: FDA's Application of Statutory Factors in Determining When a REMS Is Necessary.'' The Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85) created section 505–1 of the FD&C Act (21 U.S.C. 355–1),[1] which authorizes FDA to require a REMS for certain drugs if FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks (see section 505–1(a) of the FD&C Act). FDA can require a REMS before initial approval of a new drug application or, should FDA become aware of ''new safety information'' (as defined in section 505–1(b)(3) of the FD&C Act) about a drug and determine that a REMS is necessary to ensure that the benefits of the drug outweigh its risks, after the drug has been approved (see section 505–1(a)(2) of the FD&C Act).

FDA's determination as to whether a REMS is necessary for a particular drug is a complex, drug specific inquiry, reflecting an analysis of multiple, interrelated factors. Section 505–1(a) of the FD&C Act, as added by FDAAA, requires FDA to consider the following six factors [2] in making a decision about whether to require a REMS:

- The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug;
- The expected benefit of the drug with respect to the disease or condition;
- The seriousness of the disease or condition that is to be treated with the drug;
- Whether the drug is a new molecular entity;
- The expected or actual duration of treatment with the drug; and
- The estimated size of the population likely to use the drug.

These six factors influence FDA's decisions with respect to whether a REMS is required for a particular drug and what type of REMS might be necessary (*i.e.,* what specific elements or tools should be included as part of the REMS). FDA makes decisions about requiring a REMS as part of a benefit-risk determination for a drug after an evaluation that includes integrated consideration of each of the statutory factors. All six factors are considered together to inform FDA's REMS decision making process and no single factor is determinative as to whether a REMS is necessary. The relative importance or weight of each factor is a case specific inquiry. This guidance describes how FDA considers each of these factors in conducting its REMS analysis.

This guidance finalizes the draft guidance entitled ''FDA's Application of Statutory Factors in Determining When a REMS Is Necessary,'' issued September 21, 2016 (81 FR 64911). Interested persons were invited to comment by November 21, 2016. FDA received comments related to how we weigh the six factors when determining if a REMS is necessary, minor clarifying comments on how we apply the six factors, and comments suggesting that FDA expand on which REMS elements or tools should be used when it is determined that a REMS is necessary. FDA has considered all of the public comments received in finalizing this guidance. Clarifying edits were made to address the comments as appropriate. Additionally, edits were made to streamline the guidance, extraneous background information was removed, and the title was modified for clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''REMS: FDA's Application of Statutory Factors in Determining When a REMS Is Necessary.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

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

Dated: April 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–06663 Filed 4–4–19; 8:45 am]

BILLING CODE 4164–01–P

[1] Section 505–1 of the FD&C Act applies to applications for prescription drugs submitted or approved under subsections 505(b) (*i.e.,* new drug applications) or (j) (*i.e.,* abbreviated new drug applications) (21 U.S.C. 355(b) or (j)) of the FD&C Act and to applications submitted or licensed under section 351 (*i.e.,* biologics license applications) of the Public Health Service Act (42 U.S.C. 262). In this document, unless otherwise specified, the term ''drug'' refers to drug and biological products (or biologics).

[2] Section 505–1(a)(1) of the FD&C Act requires the Agency to consider these factors in determining whether a REMS is necessary for a new drug. FDA also generally considers these factors in determining whether (based on new safety information), a REMS is necessary for a drug that is the subject of an approved application.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–P–0047, FDA–2012–P–0468, FDA–2015–P–3400, and FDA–2016–P–1667]

Determination That ANTIVERT Chewable Tablets, 25 Milligrams, and Tablets, 12.5 Milligrams, 25 Milligrams, and 50 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that ANTIVERT (meclizine hydrochloride) chewable tablets, 25 milligrams (mg), and tablets, 12.5 mg, 25 mg, and 50 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Linda Jong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6288, Silver Spring, MD 20993–0002, 301–796–3977.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which