Third-Party Disclosure Burden

Under § 54.4(b), clinical investigators supply to the sponsor of a covered study financial information sufficient to allow the sponsor to submit complete and accurate certification or disclosure statements. Clinical investigators are accustomed to supplying such information when applying for research grants. Also, most people know the financial holdings of their immediate family and records of such interests are generally accessible because they are needed for preparing tax records. For these reasons, FDA estimates that the time required for this task may range from 5 to 15 minutes; we used the mean, 10 minutes, for the average burden per disclosure. The number of respondents is the sum of the number of affected applications multiplied by the mean of the estimated number of investigators for each application type (rounded) (see table 1 of this document).

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
54.4(b)—Clinical Investigators	7,894	1	7,894	0.17	1,342

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Our estimated burden for the information collection reflects an overall increase of 222 hours and a corresponding increase of 893 responses/records. We attribute this adjustment to an increase in the number of affected applications and the number of investigators. No program changes were made.

Dated: February 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03828 Filed 3–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1067]

Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final guidance for industry entitled ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' This guidance describes policies that FDA intends to use in evaluating bulk drug substances nominated for use in compounding under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for inclusion on the list of bulk drug substances that can be used in compounding under section 503B.

DATES: The announcement of the guidance is published in the **Federal Register** on March 4, 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–2018–D–1067 for ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding 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.

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

Submit written requests for single copies of the 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. 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: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 20993, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' Section 503B (21 U.S.C. 353b), added to the FD&C Act by the Drug Quality and Security Act in 2013, describes the conditions that must be satisfied for human drug products compounded by an outsourcing facility to be exempt from the following three sections of the FD&C Act: section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications); 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). One of the conditions that must be met for a drug product compounded by an outsourcing facility to qualify for these exemptions is that the outsourcing facility does not compound drug products using a bulk drug substance unless either: (1) It appears on a list established by the Secretary of Health and Human Services identifying bulk drug substances for which there is a clinical need (see section 503B(a)(2)(A)(i) of the FD&C Act) (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 (21 U.S.C. 356e) at the time of compounding, distribution, and dispensing (see section 503B(a)(2)(A)(ii) of the FD&C Act).

This guidance addresses 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. The guidance also addresses the factors and processes by which the Agency intends to evaluate and list bulk drug substances.

In the **Federal Register** of March 26, 2018 (83 FR 12952), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period ended on May 25, 2018. FDA received approximately 60 comments on the draft guidance. In response to received comments or on its own initiative, FDA made certain changes to the guidance. For example, FDA has further explained how Congress' limitation on bulk drug substances that can be used in compounding under section 503B helps to preserve the integrity of the new drug approval process and identified the process to request that FDA add or remove a bulk drug substance from the 503B Bulks List after the Agency has made a final determination with respect to that substance in the **Federal Register**.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

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

Dated: February 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03807 Filed 3–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments To Inform Development of a National Youth Sports Strategy

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) solicits written comments from the public on specific topics and questions that will inform the development of the National Youth Sports Strategy.

DATES: Written comments will be accepted through 11:59 p.m. E.T. on April 1, 2019.

ADDRESSES: Written public comments will be accepted via email. Instructions for submitting comments are available on the internet at *https://fitness.gov.*

FOR FURTHER INFORMATION CONTACT: Katrina L. Piercy, Ph.D., R.D., Office of Disease Prevention and Health Promotion (ODPHP), Office of the Assistant Secretary for Health (OASH), HHS; 1101 Wootton Parkway, Suite LL–100; Rockville, MD 20852; Telephone: (240) 453–8280. Email: *odphpinfo@hhs.gov*.

SUPPLEMENTARY INFORMATION: Executive Order 13824 directs the development of a National Strategy on Youth Sports and outlines the key pillars that the strategy will address. The Office of Disease Prevention and Health Promotion and the President's Council on Sports, Fitness & Nutrition are leading the development of this strategy.

Key Pillars of Youth Sports Strategy

1. Increase awareness of the benefits of participation in sports and regular physical activity, as well as the importance of good nutrition;

2. Promote private and public sector strategies to increase participation in sports, encourage regular physical activity, and improve nutrition;

3. Develop metrics that gauge youth sports participation and physical activity to inform efforts that will