Table 2 of this document provides a one-time recordkeeping burden estimate for the information to be submitted in accordance with the draft guidance. As described in the proceeding paragraphs, based on FDA's experience and industry information, FDA anticipates that 150 respondents, mainly from large volume transfusion services, will implement the recommendations set forth in section IX.A.2. Thus, based on FDA data and industry recordkeeping information, FDA estimates that the total estimated one-time recordkeeping burden is 2,400 hours.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 601.12 and 610.60 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.65, 606.100, 606.120, 606.121, 606.122, and 606.140 have been approved under OMB control number 0910–0116; and the collections of information in 21 CFR 607.3, 607.7 and 607.65 have been approved under OMB control number 0910–0052.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: December 4, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28809 Filed 12–8–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2083]

Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers.'' This draft guidance addresses new provisions in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Drug Supply Chain Security Act (DSCSA). The draft guidance describes FDA's expectations for prescription drug wholesale distributors (wholesale distributors) and third-party logistics providers (3PLs) about reporting to FDA under the DSCSA.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 9, 2015. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by February 9, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 4147, Silver Spring, MD 20993; or 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

FOR FURTHER INFORMATION CONTACT: Suzanne Barone, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *wdd3plrequirements@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers.'' This guidance is being issued to facilitate implementation of new reporting provisions under the DSCSA. On November 27, 2013, the DSCSA (Title II of Pub. L. 113–54) was signed into law. The DSCSA outlines new requirements for the licensing of prescription drug wholesale distributors and 3PLs.

Section 204 of the DSCSA amends section 503(e) of the FD&C Act (21 U.S.C. 353(e)) and outlines requirements for reporting by wholesale distributors. Section 503(e)(2)(A) of the FD&C Act (as amended) requires wholesale distributors to report annually, beginning on January 1, 2015. Information to be reported includes State licensure information and contact information for each facility. Wholesale distributors are also to report to FDA any significant disciplinary actions taken by the State or Federal Government, such as revocation or suspension of a license. Section 204 of the DSCSA also amends section 503(e)(2)(B) of the FD&C Act and requires FDA to make information about wholesale distributors' licensure available to the public on FDA's Web site. Updates to the public information are to be made on a schedule to be determined by FDA.

Section 205 of the DSCSA adds section 584 to the FD&C Act. Section 584 sets forth requirements for licensure and reporting by 3PLs. Under section 584 of the FD&C Act (as amended) (21 U.S.C. 360eee–3), 3PLs are required to report annually to FDA, beginning on November 27, 2014 (1 year after the date of enactment of the DSCSA). Third-party logistic providers are required to report State licensure information, name and address for each facility, and all trade names under which each facility conducts business.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking about information that should be submitted to FDA, the timing of the submissions, a preferred format for the submissions, and a preferred method for reporting to FDA by wholesale distributors and 3PLs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

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

We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers.

Description: On November 27, 2013, the DSCSA was signed into law. Section 503(e)(2) of the FD&C Act requires licensed wholesale distributors to report annually, beginning January 1, 2015. Information to be reported includes each State by which the wholesale distributor is licensed and the appropriate identification number of each license; and the name, address, and contact information of each facility at which, and all trade names under which, the wholesale distributor conducts business. Wholesale distributors are also required to report any significant disciplinary actions, such as revocation or suspension of a license. In addition, FDA is requesting the voluntary submission of a unique facility identifier, the expiration date of each State license, and documents associated with the disciplinary action, such as consent decree, final State Board ruling, etc.

The DSCSA also outlines reporting requirements for 3PLs. Under section 584 of the FD&C Act (as amended), 3PLs are required to report to FDA annually, beginning 1 year after the enactment of the DSCSA (November 27, 2014), the State by which a facility is licensed and the appropriate identification number and the name, address, and all trade names under which the facility conducts business. Because certain additional information will be useful to FDA in its enforcement of the Act, FDA is also requesting that 3PLs voluntarily provide the same information as wholesale distributors. The ultimate goal is for the public database to serve as a single repository of licensing and facility information for wholesale drug distributors and 3PLs conducting business in the United States.

A. Estimates of Reporters

The exact number of wholesale distributors required to report to FDA is unknown because the license status information for each wholesale distributor facility is currently maintained by each State. The DSCSA excludes several categories of businesses from the definition of wholesale distribution that may have been licensed by States as wholesale distributors before the DSCSA was enacted. FDA estimates that about 5,000 wholesale distributor facilities will report to FDA. This number is based on estimates of active wholesale facilities that distribute pharmaceuticals which include drugs, proprietaries, and sundries according to Dun & Bradstreet. This number may be an overestimation since this category may contain distributors that do not distribute prescription drugs.

The exact number of prescription drug 3PLs in the United States is also unknown because prior to the enactment of DSCSA, most states licensed 3PLs as wholesale distributors with the exception of Florida.[1] The International Warehouse Logistics Association (IWLA) has stated that the best estimate of the number of 3PLs involved with prescription drugs is indicated by the number licensed by Florida.[2] Therefore, FDA is using the number of 3PLs licensed by Florida as an estimate of the number of 3PLs in the United States. The Florida Drugs, Devices, and Cosmetics Licensee Files database (on July 16, 2014) contains 136 warehouses licensed as 3PLs, located in 28 different states. The location of each facility was verified by license number.

B. Initial Report

FDA estimates that the time and effort for wholesale distributors and 3PLs to make the initial report to FDA will be greater than reporting for subsequent reports made thereafter because of the amount of information submitted will include all State licensure information. Subsequent reports submitted to FDA will only include information that needs to be updated or added.

Each wholesale distributor must report the following information for each facility:

- Name, address, and contact information (including email address and telephone number),
- each State license and license identifying number,
- all trade names that the facility conducts business as (dba), and
- significant disciplinary actions.

In addition, FDA is requesting that wholesale distributors report the following information:

- Expiration dates for each State license,
- unique facility identifier (D–U–N–S number), and
- documents associated with the disciplinary action, such as a consent decree, final State Board ruling, etc.

3PLs should submit the same information as wholesale distributors, including significant disciplinary actions. Some of this information is required under the DSCSA to be submitted by 3PLs including name, address, State license, and State license identifying number; the other categories are voluntary for 3PLs.

The information listed above is readily available to the facilities, including the unique facility identifier. FDA currently prefers D–U–N–S number as the unique facility identification for the location of each facility. For a facility that has not been assigned a number, a number may be obtained for no cost directly from Dun & Bradstreet (*http://www.dnb.com*). Each facility may have differing

[1] Title XXXIII chapter 499 Florida statues (*http://www.flsenate.gov/laws/statutes/2011/0499.01*)

[2] ''Third-Party Logistics Providers Licensure Requirements'' Pat O'Connor, IWLA, presented at DQSA: Meeting Supply Responsibilities, Food and Drug Law Institute, February 20, 2014, Washington, DC.

numbers of State license information to input and may or may not have any significant disciplinary actions for each State. FDA is providing a Web portal for the efficient entry and submission of this information. Companies using this portal will not have to convert the information to report into an extensible markup language (XML) file in the Structured Product Label (SPL) format and submit it separately through the FDA gateway. No special computer program or expertise is required if the Web portal is used. We estimate that it will take wholesale distributors and 3PLs on average about 0.5 hours per facility to collect and input this information for the initial reporting, for a total burden for the first year of 2,568 hours. Refer to table 1.

C. Subsequent Annual Reports

FDA will maintain the information submitted previously for each facility's initial report. This information will be readily accessible through the FDA-supplied Web portal. This eliminates the need for re-entry of all of the information each year. We estimate that it will take 0.25 hours each subsequent year to review and update information such as, but not limited to, a license expiration date following renewal or a resolution of a disciplinary action. The total annual burden for wholesale distributors and 3PLs is 1,284 hours (table 2).

D. Significant Disciplinary Action Reports

Wholesale distributors are required and 3PLs are requested to report significant disciplinary actions. The number of distributors and 3PLs that will have significant disciplinary action taken against them is unknown. Disciplinary actions are currently handled by the individual States' regulatory authorities. FDA does not believe that the number of significant disciplinary actions that would limit the ability of a wholesale distributor or 3PL to warehouse and/or distribute prescription drugs would be greater than 1 percent of the total number of facilities that report on an annual basis. This would be equivalent to approximately 50 wholesale distributors and 2 3PLs. Significant disciplinary action information requested should be readily available to each wholesale distributor and 3PL involved in the action. FDA estimates that it will take 0.5 hours for the wholesale distributor or 3PL to access the system, input information, and upload documents (if available) using the Web portal. FDA estimates that the total annual burden of reporting significant disciplinary action is 26 hours (table 3).

E. Other Voluntary Reports

FDA is also requesting that a wholesale distributor or 3PL notify FDA within 30 days if a facility goes out of business or voluntarily withdraws a State or Federal license. FDA estimates that this reporting type will occur infrequently; involving five wholesale distributor facilities and one 3PL facility per year. We estimate that it will take 0.25 hours to update the company or license status. FDA estimates that the total annual burden of reporting these voluntary reports is 1.5 hours (table 4).

Description of Respondents: Respondents are prescription drug wholesale distributors and third-party logistics providers and might include small businesses in these categories.

TABLE 1—INITIAL REPORT BURDEN [1] [2]

Initial reporting to FDA	Number of respondents	Number of responses per respondent	Total initial responses	Average burden per response	Total hours
Wholesale Distributors	5,000	1	5,000	0.5 hour (30 minutes).	2,500
3PLs	136	1	136	0.5 hour (30 minutes).	68
Total					2568

[1] Any fraction is rounded up to a whole number.
[2] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—SUBSEQUENT REPORTS BURDEN [1]

Annual reporting to FDA	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
Wholesale distributors	5,000	1	5,000	0.25 hour (15 minutes).	1,250
3PLs	136	1	136	0.25 hour (15 minutes).	34
Total					1,284

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

TABLE 3—SIGNIFICANT DISCIPLINARY ACTION REPORT BURDEN [1]

Significant disciplinary actions	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
Wholesale distributors	50	1	50	0.5 hour (30 minutes).	25
3PLs	2	1	2	0.5 hour (30 minutes).	1

TABLE 3—SIGNIFICANT DISCIPLINARY ACTION REPORT BURDEN [1]—Continued

Significant disciplinary actions	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
Total					26

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

TABLE 4—OTHER VOLUNTARY REPORTS BURDEN [1]

Other voluntary reports	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
Wholesale distributors	5	1	5	0.25 hour (15 minutes).	1.25
3PLs	1	1	1	0.25 hour (15 minutes).	0.25
Total					1.50

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

F. Capital Costs

There are no capital costs associated with this collection and reporting of information if the FDA-provided Web portal is used for reporting.

III. Comments

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

IV. Electronic Access

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

Dated: December 3, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28711 Filed 12–8–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Endocrinologic and Metabolic Drugs 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 Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

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

Date and Time: The meeting will be held on January 12, 2015, from 8 a.m. to 5 p.m.

Location: College Park Marriott Hotel and Conference Center, Potomac Ballroom, 3501 University Blvd. East, Hyattsville, MD 20783. The conference center's telephone number is 301–985–7300.

Contact Person: Stephanie L. Begansky, 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, email: *EMDAC@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 committee will discuss the safety and efficacy of new drug application (NDA) 022517, proposed trade name NOCDURNA (established name: desmopressin), orally disintegrating sublingual tablets submitted by Ferring Pharmaceuticals, Inc. The proposed indication is treatment of nocturia due to nocturnal polyuria in adults who awaken two or more times each night to void.

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 committee. Written submissions may be made to the contact person on or before December 26, 2014.