

shown to be safe for use under the conditions that formed the basis upon which the applications were approved.

In the August 14, 2001, notice, FDA provided the NDA and ANDA holders an opportunity to request a hearing to show why approval of the NDAs or ANDAs should not be withdrawn. One company, KV Pharmaceutical, requested a hearing by letter dated September 13, 2001, but that request was subsequently withdrawn by letter dated October 15, 2001. No other party requested a hearing on this matter following publication of the notice in the **Federal Register**. As stated above, all products listed in the notice were subsequently discontinued.

Subsequent to the August 14, 2001, notice, one of the ANDAs listed in that notice was withdrawn. In a notice published in the **Federal Register** of February 20, 2002 (67 FR 7702), FDA withdrew approval of ANDA 71-099 for BROMATAPP Extended-Release Tablets after the application holder informed FDA that the product was no longer being marketed and requested withdrawal.

In a letter to FDA dated February 25, 2013, Pfizer requested on behalf of its subsidiaries, Wyeth Pharmaceuticals, Inc. and A.H. Robins, that FDA withdraw approval of NDA 11-694 for DIMETANE-DC under § 314.150(d), noting that the product has been discontinued and is no longer marketed. In that letter, Pfizer and its named subsidiaries waived any opportunity for a hearing provided under the August 14, 2001, notice. In a response letter of March 28, 2013, the Agency acknowledged A.H. Robins' agreement to permit FDA to withdraw approval of DIMETANE-DC under § 314.150(d) and to waive its opportunity for a hearing.

For the reasons discussed in the August 14, 2001 notice, the Director, under section 505(e)(2) of the FD&C Act and under authority delegated to her by the Commissioner, finds that new evidence of clinical experience, not contained in the applications listed in table 1 and not available at the time the applications were approved, shows that phenylpropanolamine is not shown to be safe for use under the conditions of use that formed the basis upon which the applications were approved (21 U.S.C. 355(e)(2)). Therefore, approval of the NDAs listed in table 1 is hereby withdrawn. Furthermore, the Director finds that the ANDAs listed in table 1 refer to the drugs that are the subject of the NDAs listed above. Therefore, as required under section 505(j)(6) of the FD&C Act, approval of the ANDAs listed in table 1 is also withdrawn.

Under 21 CFR 314.161 and 314.162(a)(1), FDA will remove the

products containing phenylpropanolamine named in table 1 from the list of drug products with effective approvals published in FDA's "Approved Drug Products With Therapeutic Equivalence Evaluations." FDA will not approve or accept ANDAs that refer to these drug products.

Dated: February 14, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0200]

#### Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format; Establishment of a Public Docket

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is establishing a public docket to receive information and comments on standards for the interoperable exchange of information associated with transactions involving human prescription drugs in a finished dosage form (prescription drugs) to comply with new requirements in the Drug Supply Chain Security Act (DSCSA). We are seeking information from drug manufacturers, repackagers, wholesale distributors, dispensers (primarily pharmacies) and other drug supply chain stakeholders and interested parties, including standards organizations, State and Federal Agencies, and solution providers. In particular, stakeholders and other interested parties are requested to comment about the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, for each transfer of product in which a change of ownership occurs. This action is related to FDA's implementation of the DSCSA.

**DATES:** Submit either electronic or written comments by April 21, 2014.

**ADDRESSES:** Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Connie T. Jung, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20933, 301-796-3130.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On November 27, 2013, the DSCSA (Title II, Pub. L. 113-54) was signed into law. The DSCSA outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed within the United States. Section 202 of the DSCSA, which adds section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), directs the Secretary of Health and Human Services (the Secretary) to establish standards for the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale drug distributors, dispensers, and other pharmaceutical distribution supply chain stakeholders.

FDA has been engaged in efforts to improve the security of the drug supply chain for many years to protect U.S. patients from unsafe, ineffective, and poor quality drugs. Since the formation of the first FDA Counterfeit Drug Task Force in 2003, FDA has strongly advocated for a multilayered approach to securing the supply chain and protecting consumers from the threats posed by counterfeit and diverted drugs. The ability to track and trace finished prescription drugs plays a significant role in providing transparency and accountability in the drug supply chain. Under section 505D of the FD&C Act (21 U.S.C. 355e), FDA has been evaluating existing and emerging standards, system attributes and needs, and adoption of track and trace and authentication systems and technology. The system that will be established under DSCSA will enhance FDA's ability to help protect U.S. consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful by improving detection and removal of potentially dangerous drugs from the drug supply chain.

FDA is announcing the establishment of a public docket to provide an opportunity for interested persons to

share information, current practices, research, and ideas on the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of a product and to facilitate the exchange of lot level data.

## II. Definitions

The following definitions for transaction information, transaction history, and transaction statement as defined under the DSCSA are provided to assist stakeholders in developing comments or responses. In addition, FDA is interested in learning about practices, processes, and systems that supply chain stakeholders currently use to exchange information, such as product information, information related to the sale or change of ownership of prescription drugs, or communications about drugs in distribution. For other definitions, please refer to section 202 of DSCSA.

Under DSCSA, “transaction information” means (A) The proprietary or established name or names of the product; (B) the strength and dosage form of the product; (C) the National Drug Code number of the product; (D) the container size; (E) the number of containers; (F) the lot number of the product; (G) the date of the transaction; (H) the date of shipment, if more than 24 hours after the date of transaction; (I) the business name and address of the person from whom ownership is being transferred; and (J) the business name and address of the person to whom ownership is being transferred. “Transaction history” means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product. “Transaction statement” is a statement, in paper or electronic form, that the entity transferring ownership in a transaction—(A) is authorized as required under the DSCSA; (B) received the product from a person that is authorized as required under the DSCSA; (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582 [of the DSCSA]; (D) did not knowingly ship a suspect or illegitimate product; (E) had systems and processes in place to comply with verification requirements under section 582 [of the DSCSA]; (F) did not knowingly provide false transaction information; and (G) did not knowingly alter the transaction history.

## III. Request for Comments and Information

FDA is requesting comments and supporting information on the following: (1) Current practices and ideas that may be used for the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, for each transfer of product in which a change of ownership occurs (i.e., transaction); (2) the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of a product and to facilitate the exchange of lot level data; and (3) current practices and ideas that may be used for the exchange of information between members of the pharmaceutical distribution supply chain and FDA to provide, receive, and terminate notifications, respond to requests for verification of product, and respond to requests for information from FDA or other appropriate Federal or State officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product.

To facilitate this discussion, FDA has included several questions in the following paragraphs. These questions, which are not meant to be exhaustive, are provided to stimulate public comments that will help FDA establish initial standards for the interoperable exchange of information for tracing of prescription drugs in paper or electronic format. The public is encouraged to address these and/or other related issues.

*Questions related to (1) current practices and suggestions for the interoperable exchange of transaction information, transaction history, and transaction statements and (2) the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of prescription drugs and to facilitate the exchange of lot level data:*

1. What types of information about transactions do you exchange? What practices, processes, or systems, either paper-based or electronic, do supply chain stakeholders use to exchange this information? Are the practices, processes, or systems based on a standard? Are they interoperable with other systems that supply chain stakeholders may be using?

2. What practices, processes or systems, either paper-based or electronic, do supply chain stakeholders use to exchange information related to prior transactions? Are the practices, processes, or systems based on a standard? Are they interoperable with other systems that supply chain stakeholders may be using?

3. Do the practices, processes, or systems that supply chain stakeholders use to exchange transaction information or transaction histories include or have the ability to include lot level data?

4. If you are currently using paper means to exchange transaction information or history, when do you plan to move to an electronic format?

5. Are there challenges to adopting and using a system, in paper or electronic format, for the interoperable exchange of transaction information or history? How can these challenges be addressed?

6. Are there practices, processes, or systems that supply chain stakeholders can use now to exchange the information in the transaction statement required by the DSCSA?

7. Are there challenges to providing the transaction statement to supply chain stakeholders in either paper or electronic form? How can these challenges be addressed?

8. Are there standards or current practices that you would recommend for FDA to consider as a model for providing any or all of the transaction information, transaction history, or transaction statement to other supply chain stakeholders?

9. Are there other technologies, systems, or solutions available now that would enable the interoperable exchange of transaction information, transaction history, or transaction statements?

*Questions related to (3) current practices and suggestions for the exchange of information between supply chain stakeholders or with FDA to provide, receive, and terminate notifications, respond to requests for verification of suspect product, and respond to requests for information from FDA or other appropriate Federal or State officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product:*

10. Are there current practices, processes, or systems that could be used to exchange information between supply chain stakeholders and FDA with respect to providing, receiving, and terminating a notification that an illegitimate product is found in distribution? Are these practices, processes, or systems effective? If not, please provide recommendations to

improve these practices, processes, or systems.

11. Are there current practices, processes, or systems that could be used to exchange information between supply chain stakeholders or with FDA to respond to requests to verify the lot number, expiration date, and other indices of identity assigned to a product by the manufacturer or repackager (i.e., requests for verification of suspect product)? Are these practices, processes, or systems effective? If not, please provide recommendations to improve these practices, processes, or systems.

12. Are there current practices, processes, or systems that could be used for providing information in response to requests from FDA or other appropriate Federal or State officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product? Are these practices, processes, or systems effective? If not, please provide recommendations to improve these practices, processes, or systems.

*Question related to capturing information that has not necessarily been addressed by the previous questions:*

13. Are there other considerations related to standards for the interoperable exchange of information for tracing of human, finished, prescription drugs that have not been addressed by the previous questions? Please provide any additional information that you think could be helpful for the Agency to consider as it implements these provisions of the DSCSA.

### III. Submission of 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>.

Dated: February 13, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-03592 Filed 2-19-14; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Notice of Diabetes Mellitus Interagency Coordinating Committee Meeting

**SUMMARY:** The Diabetes Mellitus Interagency Coordinating Committee (DMICC) will hold a meeting on March 12, 2014 from 1:00 to 4:00 p.m. at the Natcher Conference Center (Building 45) Conference Room E1/E2, on the NIH Campus in Bethesda, MD. The topic for this meeting will be "Future Needs and Direction of Surveillance of Diabetes in Youth and Young Adults." The meeting is open to the public.

**DATES:** The meeting will be held on March 12, 2014 from 1:00 to 4:00 p.m. Individuals wanting to present oral comments must notify the contact person at least 10 days before the meeting date.

**ADDRESSES:** The meeting will be held at the Natcher Conference Center (Building 45) Conference Room E1/E2, on the NIH Campus in Bethesda, MD.

**FOR FURTHER INFORMATION CONTACT:** For further information concerning this meeting, see the DMICC Web site, [www.diabetescommittee.gov](http://www.diabetescommittee.gov), or contact Dr. B. Tibor Roberts, Executive Secretary of the Diabetes Mellitus Interagency Coordinating Committee, National Institute of Diabetes and Digestive and Kidney Diseases, 31 Center Drive, Building 31A, Room 9A19, MSC 2560, Bethesda, MD 20892-2560, telephone: 301-496-6623; FAX: 301-480-6741; email: [dmicc@mail.nih.gov](mailto:dmicc@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** The DMICC, chaired by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) comprising members of the Department of Health and Human Services and other federal agencies that support diabetes-related activities, facilitates cooperation, communication, and collaboration on diabetes among government entities. DMICC meetings, held several times a year, provide an opportunity for Committee members to learn about and discuss current and future diabetes programs in DMICC member organizations and to identify opportunities for collaboration. The March 12, 2014 DMICC meeting will focus on "Future Needs and Direction of Surveillance of Diabetes in Youth and Young Adults."

Any member of the public interested in presenting oral comments to the Committee should notify the contact person listed on this notice at least 10

days in advance of the meeting. Interested individuals and representatives or organizations should submit a letter of intent, a brief description of the organization represented, and a written copy of their oral presentation in advance of the meeting. Only one representative of an organization will be allowed to present; oral comments and presentations will be limited to a maximum of 5 minutes. Printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the Committee by forwarding their statement to the contact person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Because of time constraints for the meeting, oral comments will be allowed on a first-come, first-serve basis.

Members of the public who would like to receive email notification about future DMICC meetings should register for the listserv available on the DMICC Web site, [www.diabetescommittee.gov](http://www.diabetescommittee.gov).

Dated: February 12, 2014.

**B. Tibor Roberts,**

*Executive Secretary, DMICC, Office of Scientific Program and Policy Analysis, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.*

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## DEPARTMENT OF THE INTERIOR

### Office of the Secretary

[DR.5B211.IA000713]

#### List of Programs Eligible for Inclusion in Fiscal Year 2014 Funding Agreements To Be Negotiated With Self-Governance Tribes by Interior Bureaus Other Than the Bureau of Indian Affairs

**AGENCY:** Office of the Secretary, Interior.

**ACTION:** Notice.

**SUMMARY:** This notice lists programs or portions of programs that are eligible for inclusion in Fiscal Year 2014 funding agreements with self-governance Indian tribes and lists programmatic targets for each of the non-Bureau of Indian Affairs (BIA) bureaus in the Department of the Interior, pursuant to the Tribal Self-Governance Act.

**DATES:** This notice expires on September 30, 2014.

**ADDRESSES:** Inquiries or comments regarding this notice may be directed to