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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 2004N–0115]

Prescription Drug Importation; Public Meeting and Establishment of Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and establishment of docket.

The Food and Drug Administration (FDA), on behalf of the U.S. Department of Health and Human Services' (HHS) Task Force on Drug Importation, is announcing that it is establishing a docket to receive information and comments on certain issues related to the importation of prescription drugs. FDA is also announcing a public meeting to enable interested individuals, organizations, and other stakeholders to present information to the Task Force for consideration in the study on importation mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The Task Force is particularly interested in information related to whether and under what circumstances drug importation could be conducted safely, and what its likely consequences would be for the health, medical costs, and development of new medicines for American patients.

Date and Time: The public meeting will be held on April 14, 2004, from 9 a.m. to 5 p.m.

Location: The public meeting will be held at the Natcher Auditorium, Building 45, National Institutes of Health (NIH), 9000 Rockville Pike, Bethesda, MD 20892. Parking will be limited and there may be delays entering the NIH campus due to increased security. We recommend arriving by Metro if

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possible. NIH is accessible from the Metro's red line at the Medical Center/ NIH stop.

Contact Person: Karen Strambler, Office of Policy, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, e-mail: *Karen.Strambler@fda.gov*.

Registration and Requests for Oral Presentation: No registration is required to attend the public meeting. Seating will be on a first-come, first-serve basis. If you wish to present at the public meeting, please submit your request and a summary of your presentation to Karen Strambler the contact person listed in this document. Requests should be identified with the docket number listed in brackets in the heading of this document. (To ensure timely handling, the outer envelope should be clearly marked with the docket number listed in brackets in the heading of this document and the statement "Prescription Drug Importation Public Meeting.'')

Speakers must submit requests for presentations along with a short summary of their presentation by close of business on March 30, 2004. Presenters must send final electronic presentations, if any, in Powerpoint, Microsoft Word, or Adobe Portable Document Format (PDF) to Karen Strambler the contact person listed in this document by close of business on April 7, 2004.

The public docket will formally remain open until June 1, 2004, and we encourage commenters to submit written and electronic comments before that date. However, FDA recognizes that there may be a need for further public input, and will be prepared to accept additional comments beyond this date as necessary. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written comments to the Division of Dockets Management

(HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Requests to present should contain the following information:

- Presenter's name;
- Address;
- Telephone number;
- E-mail address;
- Fax number;
- Affiliation, if any;
- Summary of the presentation; and
- Approximate amount of time requested for the presentation.

FDA encourages persons and groups having similar interests to consolidate their information and present it through a single representative, if possible, to enable a broad range of views to be presented. After reviewing the requests to present, the agency will schedule each appearance and notify each participant by e-mail or telephone of the time allotted to the participant and the approximate time the participant's presentation is scheduled to begin.

Presenters must send final electronic presentations, if any, in Microsoft Powerpoint, Microsoft Word, or PDF to Karen Strambler the contact person listed in this document by close of business on April 7, 2004,

If you need special accommodations due to disability, please inform Elizabeth French, Office of Policy (HF–11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, rm. 14–101, Rockville, MD 20857, 301–827–3360, FAX: 301–594–6777, e-mail: *efrench@oc.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On December 8, 2003, President Bush signed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Medicare Modernization Act) (Public Law 108–173). Section 1121 of this legislation gives the Secretary of HHS (the Secretary) the authority to implement a system in the United States for the importation of Canadian prescription drugs. However, the Secretary is permitted to implement such a system only if he is first able to certify to the Congress that it would be safe and cost-effective. Section 1122 of this legislation also directs the Secretary to conduct a study that examines whether and under what circumstances drug importation could be conducted safely, and what its likely consequences would be for the health, medical costs, and development of new medicines for American patients. To comply with the Congressional mandate, the Secretary has formed the Task Force on Drug Importation to advise and assist HHS in this study. The Task Force plans to consider several issues in the study, including several that Congress specifically asked HHS to consider. To assist in this effort we are asking for public comment on the following issues, which the Conference Report to the Medicare Modernization Act directs us to address in the study:

• *Impact of Unapproved Drugs:* What is the scope and volume of unapproved drugs entering the United States through mail shipments and at border crossings? What are the safety concerns posed by these products? What evidence exists to substantiate these concerns? Can they be quantified? What is the scope and volume of FDA-approved drugs commercially available in other countries?

• *FDA's* Ability *to Assure Safety*: What should FDA do to assure safety of imported products? Should FDA examine all imports, or should a sampling

method, along with testing, be used to assure safety? What resources would FDA need for different levels of oversight, which could include visual inspection, sampling, and other testing methods to determine quality? Is there a need for, and what is the feasibility of, modifications to the U.S. pharmaceutical distribution system that would help to ensure the safety of drug products imported into the United States under section 1121 of the Prescription Drug, Improvement and Modernization Act of 2003?

• *Regulatory/Legislative Issues:* What, if any, limitations in current legal authorities, such as sections 505, 502, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355, 352, and 381), may inhibit the Secretary's ability to certify that prescription drugs imported into the United States from Canadian wholesalers or pharmacies are safe? What, if any, limitations in current legal authorities may inhibit the Secretary's ability to certify whether the imported drugs comply with sections 505, 502, and 501 of the act (21 U.S.C. 351) (e.g., Are the drugs approved by FDA?, Do they contain appropriate labeling?, Are they manufactured according to current Good Manufacturing Practice)? If FDA could not assure the same level of safety for imported drugs as consumers expect from drugs purchased at a State-licensed pharmacy, what level of risk would be acceptable?

In what ways would importation of drugs, if permitted under section 1121 of the Medicare Modernization Act, impact U.S. and international intellectual property rights as well as obligations under existing trade agreements? Are there additional legal protections needed for effective enforcement of these rights and agreements?

• *Technology:* What anti-counterfeiting technologies are available and feasible to use to improve the safety of products in the domestic market as

well as to prevent the importation of unapproved or counterfeited drug products? What costs would be associated with the implementation of such technologies?

• *Financial Impact*: What would be the short and long term financial impact on drug prices, on drug manufacturers, on pharmacies, on wholesalers, and on patients if section 1121 were to be implemented? What other system costs could be associated with importation of pharmaceuticals from Canada and other countries into the United States?

• *Research and Development:* What would be the impact on research and development of drugs and the associated impact on consumers and patients, if section 1121 of the Prescription Drug, Improvement and Modernization Act of 2003 were to be implemented? Would a reduction in domestic pharmaceutical sales result over time in reduced investment in developing new drugs for the future?

• *Liability Issues:* What, if any, liability concerns would exist for entities in the U.S. pharmaceutical distribution system if importation of drugs from Canada or another country were permitted? If liability concerns do exist, what liability protections do you believe should be implemented?

• *Regulation by Foreign Health Agencies:* What protections do other countries have in place to ensure the safety of drugs that are exported or transshipped from their country to the United States? If these protections are lacking, to what extent are foreign health agencies willing or able to implement new or additional protections to ensure safety of exported or transshipped drugs?

II. Comments

Interested persons should submit to the Division of Dockets Management (see *Registration and Requests for Oral Presentation)* written or electronic

comments regarding this document by June 1, 2004. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be reviewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

111. Transcripts

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page or a CD at a cost of $14.25 each.

IV. Electronic Access

Persons with access to the Internet may obtain additional information on the public meeting at *http://www.fda.gov/importeddrugs.*

Dated: 3·15·04

March 15, *2004*

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04;8:45 am]

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