

products for the educational benefit of FDA and attendees. The objective of the meeting is for FDA to gather information to assist FDA's counterfeit drug task force in finalizing its report, which will include recommendations on steps that FDA, other government agencies, and the private sector can take to minimize the risks to the public from counterfeit drugs entering the supply chain.

DATES AND TIME: The public meeting and vendor display will be held on October 15, 2003, from 9 a.m. to 5 p.m. Attendees should send notice of intent to attend the meeting by October 9, 2003. Speakers must register and submit a short summary of the presentation by September 24, 2003. Presenters must send final electronic presentations in Microsoft PowerPoint, Microsoft Word, or Adobe Portable Document Format (PDF) to FDA by close of business on October 3, 2003.

However, written and electronic comments will be accepted for consideration until November 3, 2003. Vendors must register and submit a brief summary of the product(s) they plan to display by close of business September 24, 2003.

ADDRESSES: The public meeting and vendor display will be held at the Four Points Sheraton Bethesda, 8400 Wisconsin Ave., Bethesda, MD 20814, 301-654-1000. The hotel may be reached by Metro using the Medical Center Station on the red line, which is 2 1/2 blocks from the hotel; or you may call the hotel for shuttle bus service. Notice of intent to attend the meeting and requests to present at the meeting should be sent to Elizabeth French, Office of Policy (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360, FAX 301-594-6777, e-mail: efrench@oc.fda.gov. Requests for vendor display at the meeting should be sent to Karen Strambler, Office of Policy (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360, FAX 301-594-6777, e-mail: kstrambler@oc.fda.gov.

Registration and Requests for Presentation: If you wish to attend the meeting, please notify Elizabeth French (see **ADDRESSES**). If you wish to present at the public meeting, please submit your request and a summary of your presentation to Elizabeth French at FDA (see **ADDRESSES**). Requests should be identified with the docket number listed in the heading of this document.

Requests to present should contain the following items:

- Presenter's name;
 - Address;
 - Telephone number;
 - E-mail address;
 - 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 intends to schedule each appearance and notify each participant by e-mail or telephone of the time allotted to the person and the approximate time the person's presentation is scheduled to begin.
- Presenters must send final electronic presentations in Microsoft PowerPoint, Microsoft Word, or PDF to FDA by close of business on October 3, 2003.
- Registration and Request for Vendors Displays:**
- In addition, there will be an opportunity for vendors of authentication and track and trace anti-counterfeiting technologies to display their products in a room adjacent to the public meeting. The purpose of these displays is to educate FDA and other attendees of the types of anti-counterfeit technologies that are currently available. FDA is particularly interested in vendors displaying products that have the following features:
- Product is currently in commercial use or production;
 - Product (or closely similar product) is currently being used in the pharmaceutical distribution system or that has clear applicability to authenticating or tracking pharmaceuticals (e.g., are easily incorporated into the manufacturing process, packaging, and/or labeling of drugs and biologics);
 - Track/trace products that have the ability to locate the product throughout the distribution chain from the time of manufacture to the time sale to a consumer;
 - Track/trace products that have the ability to be read and used by each entity (or individual) having physical contact with the pharmaceutical;
 - Covert authentication technologies that are identifiable by one or more points in the distribution chain (i.e. by wholesalers, repackers, retailers, and health care entities); and
 - Covert forensic technologies that are identifiable by a sophisticated analytical laboratory and the manufacturer.
- FDA is not interested in having technologies displayed that are not in production or current commercial use, and that are not applicable to pharmaceuticals. For example, technologies that are not easily

incorporated into the manufacture, packaging, and/or labeling of pharmaceuticals may not be appropriate for display. Vendors should take these factors into account prior to determining which products to display.

Because of limited space availability, all vendor requests may not be accommodated. If you wish to have a display at the public meeting, please submit your request and the following information to Karen Strambler (see **ADDRESSES**). Requests should be identified with the docket number listed in the heading of this document. Space available for display will be determined based on the number of registrants and total space available; however, the agency anticipates that of those that can be accommodated, vendors will each be provided with, at a minimum, a 4- by 3-foot table for table top display.

Requests to display should contain the following items:

- Presenter's name,
- Address,
- Telephone number,
- Affiliation,
- Product(s) for display, and
- Brief summary of how the anti-counterfeit technology meets the criteria listed in the previous list items.

After reviewing the requests to display, FDA intends to notify each vendor by e-mail or telephone whether there is space available for display.

For Information Regarding This Notice: Poppy Kendall, Office of Policy (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-9278, FAX 301-594-6777, e-mail: poppy.kendall@fda.gov.

If you need special accommodations due to disability, please inform Elizabeth French (see **ADDRESSES**).

SUPPLEMENTARY INFORMATION:

I. Background

Counterfeit drugs pose potentially serious public health and safety concerns. They may contain only inactive ingredients, incorrect ingredients, improper dosages, dangerous subpotent or superpotent ingredients, or even adventitious agents or contaminants such as harmful bacteria. In the United States, drug counterfeiting is a relatively rare event. Although FDA believes domestic counterfeiting is not widespread, the agency has recently seen an increase in counterfeiting activities as well as a more sophisticated ability to introduce finished dosage counterfeits into the otherwise legitimate drug distribution channels. During the late 1990's, FDA counterfeit drug investigations averaged about five per year. Since 2000,