

Dated: August 19, 2003.

**Nancy E. Cheal,**

*Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0361]

#### Anti-counterfeit Drug Initiative

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that it is establishing a docket to receive information and comments on the agency's initiative against counterfeit drugs. Many individuals, vendors, trade and professional associations, consumer groups, and other stakeholders have offered to assist FDA. This action is intended to ensure that there is a venue for information and comments to be submitted to the agency regarding the anti-counterfeit initiative.

**DATES:** The agency encourages interested parties to submit information by November 30, 2003.

**ADDRESSES:** Submit written comments and information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. All comments submitted to the public docket are public information and may be posted to FDA's Web site (<http://www.fda.gov>) for public viewing. Please include the docket number listed in the heading of this document on all correspondence related to this docket.

**FOR FURTHER INFORMATION CONTACT:** Poppy Kendall, Office of Policy (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360, e-mail: [pkendall@fda.gov](mailto:pkendall@fda.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Counterfeit drugs pose potentially serious public health and safety concerns. They may contain only inactive ingredients, incorrect ingredients, improper dosages, or even dangerous subpotent or superpotent ingredients. 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. FDA has seen its counterfeit drug investigations increase to over 20 per year since 2000, after averaging only about 5 per year through the late 1990's.

In an effort to protect against the rising occurrence of potentially unsafe counterfeit drugs reaching consumers, on July 16, 2003, FDA announced an initiative to more aggressively protect American consumers from the risks posed by counterfeit drugs. As part of this effort, FDA established an internal task force that will develop recommendations for steps FDA, other government agencies, and the private sector can take to minimize the risks to the public from counterfeit drugs getting into the supply chain. Some of the areas that FDA's task force will explore include the following topics:

- *Technology:* Assess the extent to which new technologies can help assure the authenticity of drugs;
- *Regulatory/Legislative Issues:* Will evaluate potential regulatory and legislative changes that could be made to strengthen the nation's protections against counterfeiting;
- *Public Education:* Recommend ways to educate consumers and health providers on steps they can take to minimize risks associated with counterfeit drugs; will also educate consumers and health professionals about what to look for and what to do if they suspect they have received a counterfeit drug;

- *Industry and Health Professional Issues:* Identify actions industry and health professionals can take to prevent, detect, and respond to counterfeit drugs;

The task force has the following deliverables:

- Interim task force report to be released in September 2003. It will include draft recommendations on which interested persons may comment.
- Public meeting to be held in mid-October 2003. The meeting announcement will be published in a forthcoming **Federal Register** and will pose issues for discussion at the meeting.
- Final task force report to be released in January 2004.

Many individuals, vendors, trade and professional associations, consumer groups, and other stakeholders have offered to assist the agency and provide information that may be helpful in the agency's anti-counterfeit drug efforts. The agency requests that all persons or

organizations that would like to provide such information submit it to this docket number.

FDA expects to place submissions it receives on this initiative in the public docket. Therefore, submitters should recognize that information submitted to this docket is public information and can be viewed and accessed by the general public.

Note that, as mentioned previously, the counterfeit task force expects to issue a report with draft recommendations for public comment in September of this year. In addition, the agency expects to hold a public meeting on these issues later this year as well. Comments on the draft report and the issues discussed at the public meeting will sought in future issues of the **Federal Register**.

Dated: August 19, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources And Services Administration

#### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques