

Respondents: States.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Survey .....	51	1	3.75	191.25

*Estimated Total Annual Burden Hours:* 191.25.

**Additional Information:** Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

**OMB Comment:** OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Ms. Wendy Taylor.

Dated: April 14, 1998.

**Bob Sargis,**

*Acting Reports Clearance Officer.*

[FR Doc. 98-10444 Filed 4-20-98; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. 98N-0194]

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

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for

public comment in response to the notice. This notice solicits comments on the voluntary registration of cosmetic product establishments with FDA.

**DATES:** Submit written comments on the collection of information by June 22, 1998.

**ADDRESSES:** Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Margaret R. Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (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.

##### Registration of Cosmetic Product Establishment—21 CFR Part 710 (OMB Control Number 0910-0027—Extension)

Under the Federal Food, Drug, and Cosmetic Act (the act), cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, FDA requests that establishments that manufacture or package cosmetic products register with the agency on Form FDA 2511 "Registration of Cosmetic Product Establishment." Regulations providing procedures for the voluntary registration of cosmetic product establishments are found in 21 CFR part 710.

Because mandatory registration of cosmetic establishments is not authorized by statute, voluntary registration provides FDA with the best information available about the location, business trading names used, and the type of activity (manufacturing or packaging) of cosmetic product establishments that participate in this program. In addition, the registration information is an essential part of planning onsite inspections to determine the scope and extent of noncompliance with applicable provisions of the act. The registration information is used to estimate the size of the cosmetic industry regulated. Registration is permanent, although FDA requests that firms submit an amended registration on Form FDA 2511 if any of the information originally submitted changes.

FDA uses registration information as input for a computer data base of cosmetic product establishments. This data base is used for mailing lists to distribute regulatory information or to invite firms to participate in workshops on topics they may be interested in.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Part	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
710	FDA 2511	50	1	50	0.4	20

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates are based on past experience and on discussions with registrants during routine communications. FDA receives an average of 50 registration submissions annually. There has been no change over the past 13 years in the number of submissions of Form FDA 2511 or in the time it takes to complete this form.

Dated: April 14, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98N-0148]

#### International Drug Scheduling; Convention on Psychotropic Substances; Dihydroetorphine, Ephedrine, and Remifentanyl; Isomers of Psychotropic Substances

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

**ACTION:** Notice; correction.

The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of March 18, 1998 (63 FR 13258). The document announced an upcoming World Health Organization review of three substances. The document was published with an error. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Nicholas P. Reuter, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1696, E-mail: NReuter@bangate.fda.gov.

In FR Doc. 98-6910, beginning on page 13258 in the **Federal Register** of Wednesday, March 18, 1998, the following correction is made:

1. On page 13259, in the first column, in the fourth full paragraph, the second sentence "Remifentanyl is approved in the United States as an anesthetic for

use in animals and is controlled domestically as a narcotic in schedule II of the CSA." is corrected to read as follows: "Remifentanyl is approved in the United States as an anesthetic and is controlled domestically as a narcotic in schedule II of the CSA."

Dated: April 14, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Science Advisory Board to the National Center for Toxicological Research; 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). At least one portion of the meeting will be closed to the public.

**Name of Committee:** Science Advisory Board to the National Center for Toxicological Research (NCTR).

**General Function of the Committee:** To provide advice and recommendations to the agency on FDA regulatory issues.

**Date and Time:** The meeting will be held on May 6, 1998, 9 a.m. to 5 p.m., and May 7, 1998, 9 a.m. to 11 a.m.

**Location:** NCTR, Jefferson, AR.

**Contact Person:** Ronald F. Coene, NCTR (HFT-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6696, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12559. Please call the Information Line for up-to-date information on this meeting.

**Agenda:** The board will be presented with draft reports on evaluations of three of NCTR's programs in

Information Technology, Biometry and Risk Assessment, and Neurotoxicology for their review, discussion, and approval. The draft reports are the products of three site visit teams who conducted onsite reviews over the last 9 months. The staff from these programs will provide a preliminary response to the issues raised and recommendations made. A progress report will be presented to the board on the recommendations it made at its last meeting on NCTR's Estrogen Knowledge Base project. Also, there will be a Center Director's update.

**Procedure:** On May 6, 1998, from 9 a.m. to 5 p.m., and May 7, 1998, from 9 a.m. to 11 a.m., the meeting is open to the public. 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 by April 17, 1998. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m., on May 7, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 17, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

**Closed Committee Deliberations.** On May 7, 1998, from 1 p.m. to 2:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

The Commissioner approves the scheduling of meetings at locations outside of the Washington, DC, area on the basis of the criteria of 21 CFR 14.22 of FDA's regulations relating to public advisory committees.