

to the contemplated license should be directed to Andrew Watkins, Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K-79, Atlanta, GA 30341, telephone: (770) 488-8600; facsimile: (770) 488-8615. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by CDC within sixty days of this notice will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552. A signed Confidential Disclosure Agreement will be required to receive a copy of any pending patent application.

Dated: January 27, 2003.

**Joseph R. Carter,**

*Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).*

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**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02N-0454]

#### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Notice of a Claim for Generally Recognized as Safe Exemption Based on a Generally Recognized as Safe Determination

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by March 5, 2003.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

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

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed

collection of information to OMB for review and clearance.

#### Notice of a Claim for GRAS Exemption Based on a GRAS Determination (OMB Control Number 0910-0342)—Extension

**Description:** Section 409 of the act (21 U.S.C. 348) establishes a premarket approval requirement for “food additives;” section 201(s) of the act (21 U.S.C. 321) provides an exemption from the definition of “food additive” and thus from the premarket approval requirement, for uses of substances that are generally recognized as safe (GRAS) by qualified experts. FDA is proposing a voluntary procedure whereby members of the food industry who determine that use of a substance satisfies the statutory exemption may notify FDA of that determination. The notice would include a detailed summary of the data and information that support the GRAS determination, and the notifier would maintain a record of such data and information. FDA would make the information describing the GRAS claim, and the agency’s response to the notice, available in a publicly accessible file; the entire GRAS notice would be publicly available consistent with the Freedom of Information Act and other Federal disclosure statutes.

**Description of Respondents:** Manufacturers of Substances Used in Food and Feed.

In the **Federal Register** of October 31, 2002 (67 FR 66404), the agency requested comments on the proposed collection of information. No comments were received that pertained to this collection of information.

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

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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.36	50	1	50	150	7,500
570.36	10	1	10	150	1,500
Total					9,000

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
170.36(c)(v)	50	1	50	15	750
570.36(c)(v)	10	1	10	15	150
Total					900

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

The reporting requirement is for a proposed rule (62 FR 18937, April 17, 1997) that has not yet been issued as a final rule. In developing the proposed rule, FDA solicited input from representatives of the food industry on the reporting requirements, but could not fully discuss with those representatives the details of the proposed notification procedure. FDA received no comments on the agency's estimate of the hourly reporting requirements, and thus has no basis to revise that estimate at this time. During 1998, FDA received 12 notices that were submitted under the terms of the proposed rule. FDA received 23 notices in 1999, 30 notices in 2000, and 28 notices in 2001. To date, the number of annual notices is less than FDA's estimate; however, the number of annual notices could increase when the proposed rule becomes final.

Dated: January 28, 2003.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-2458 Filed 1-31-03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 03N-0015]

#### International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization Scheduling Recommendation for Amineptine (7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid)

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is providing interested persons with the opportunity to submit written comments concerning a recommendation by the World Health Organization (WHO) to impose international manufacturing and distribution restrictions, under international treaties, on a drug substance. The comments received in response to this notice will be considered in preparing the U.S. position on this proposal for a meeting of the United Nations Commission on Narcotic Drugs (CND) in Vienna, Austria, April 8 to 17, 2003. This notice is issued under the Controlled Substances Act.

**DATES:** Submit written or electronic comments by March 1, 2003.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. To ensure expeditious review of written comments, send a copy by facsimile or e-mail to: James R. Hunter (see following address).

**FOR FURTHER INFORMATION CONTACT:**

James R. Hunter, Controlled Substances Staff (HFD-9) Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2098, FAX: 301-443-9222, e-mail: [hunterj@cder.fda.gov](mailto:hunterj@cder.fda.gov).

**SUPPLEMENTARY INFORMATION:**

#### I. Background

The United States is a party to the 1971 Convention on Psychotropic Substances (the Convention). Section 201(d)(2)(B) of the Controlled Substances Act (the CSA) (21 U.S.C. 811(d)(2)(B)) provides that when the United States is notified under Article 2 of the Convention that CND proposes to decide whether to add a drug or other substance to one of the schedules of the Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State must transmit notice of such information to the Secretary of Health and Human Services (HHS). The Secretary of HHS must then publish a summary of such information in the **Federal Register** and provide opportunity for interested persons to submit comments. The Secretary of HHS must then evaluate the proposal and furnish a recommendation to the Secretary of State that shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

As detailed in the following paragraphs, the Secretary of State has received notification from the Secretary-General of the United Nations (the Secretary-General) regarding a substance to be considered for control under the Convention. This notification reflects the recommendation from the 33d WHO Expert Committee for Drug Dependence (ECDD), which met September 14 to 16, 2002. In the **Federal Register** of April 9, 2002 (67 FR 17074), FDA announced the WHO ECDD review and invited interested persons to submit information for WHO's consideration.

The full text of the notification from the Secretary-General is provided in section II of this document. Section 201(d)(2)(B) of the CSA requires the Secretary of HHS, after receiving a

notification proposing scheduling, to publish a notice in the **Federal Register** to provide the opportunity for interested persons to submit information and comments on the proposed scheduling action.

#### II. United Nations Notification

The formal United Nations notification that identifies the drug substance and explains the basis for the recommendation is reproduced below.

*Notification on amineptine:*

Reference: NAR/CL.12/2002 CS18/02 CU 2002/262.

The Secretary-General of the United Nations presents his compliments to the Secretary of State of the United States of America and has the honour to inform the Government that the World Health Organization (WHO), pursuant to article 2, paragraphs 1 and 4 of the Convention on Psychotropic Substances, 1971, has notified him that it is of the opinion that amineptine should be placed in Schedule II of that Convention.

Article 2, paragraphs 1 and 4, of the Convention read:

1. If a Party or the World Health Organization has information relating to a substance not yet under international control which in its opinion may require the addition of that substance to any of the Schedules of this Convention, it shall notify the Secretary-General and furnish him with the information in support of that notification. The foregoing procedure shall also apply when a Party or the World Health Organization has information justifying the transfer of a substance from one Schedule to another among those Schedules, or the deletion of a substance from the Schedules."

"4. If the World Health Organization finds: (a) That the substance has the capacity to produce (i)(1) a state of dependence, and (2) central nervous system stimulation or depression, resulting in hallucinations or disturbances in motor function or thinking or behaviour or perception or mood, or (ii) similar abuse and similar ill effects as a substance in Schedule I, II, III or IV, and (b) That there is sufficient evidence that the substance is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control, the World Health Organization shall communicate to the Commission an assessment of the substance, including the extent or likelihood of abuse, the degree of seriousness of the public health and social problem and the degree of usefulness of the substance in medical therapy, together with recommendations on control measures, if any, that would be appropriate in the light of its assessment."

In accordance with the provisions of article 2, paragraph 2, of the 1971 Convention, the Secretary-General hereby transmits the text of that notification as an annex to the present note. The notification together with the assessments and recommendations from WHO as well as any data received from governments on that substance, will also be brought to the attention of the Commission