

in the presentation of comparative drug claims to ensure that consumers understand and may critically evaluate them?

4. Reminder advertisements, by definition, lack contextual and risk information. What role do such advertisements play in consumer promotion? Are such advertisements useful for consumers?

5. (a) Current regulations require inclusion of a "brief summary" of prescribing information in print advertisements. Is this form of disclosure effective for consumers? Is it informative? Should there be alternate requirements for risk disclosure, and, if so, what should they be? (b) Current regulations require that broadcast advertisements present a "brief summary" of prescribing information unless adequate provision is made for the dissemination of the approved product labeling. Also required is a statement of the major risks of the product. Are these disclosure requirements effective and informative for consumers? Are there alternate types of risk disclosures that are more effective or informative? If so, what are they?

6. New technologies have spurred the growth of computer-based promotional vehicles, such as electronic bulletin boards, kiosks in pharmacies, the Internet, etc. These promotions are neither purely print nor broadcast. What disclosure requirements, in general, should be used for such consumer-directed prescription drug promotion?

7. "Infomercials" are program-length television or radio programs that promote prescription drugs to consumers. What restrictions and/or disclosures should be required of infomercials promoting prescription drugs to consumers?

8. To help ensure that advertisements will be in "fair balance," FDA currently requests disclosure of key risk and/or limitations of efficacy information, i.e., critical messages, in consumer-directed prescription drug promotion. In general, are such disclosures effective and informative for this audience? What kinds of information should be disclosed?

9. Some manufacturer-supported direct-to-consumer promotion appears to be sponsored by independent, third-party services, such as mailings from disease-specific foundations or disease management support services. What disclosures should be required to inform consumers of the source of the communication?

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Commissioner of Food and Drugs or his designee. The presiding officer will be accompanied by a panel of Public Health Service employees with relevant expertise.

Persons who wish to participate in the part 15 hearing must file a written notice of participation with the Dockets Management Branch (address above) by September 15, 1995. To ensure timely handling, the outer envelope should be clearly marked with docket number 95N-0227 and the statement "Direct-to-Consumer Hearing." Groups should submit two copies. The notice of participation should contain the person's name; address; telephone number; affiliation, if any; brief summary of the presentation; and approximate amount of time requested for the presentation. The agency requests that interested persons and groups having similar interests consolidate their comments and present them through a single representative. FDA will allocate the time available for the hearing among the persons who file notices of participation as described above. If time permits, FDA may allow interested persons attending the hearing who did not submit a written notice of participation in advance to make an oral presentation at the conclusion of the hearing.

After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by telephone of the time allotted to the person and the approximate time the person's presentation is scheduled to begin. The hearing schedule will be available at the hearing. After the hearing, the schedule will be placed on file in the Dockets Management Branch under docket number 95N-0227.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. The presiding officer and any panel members may question any person during or at the conclusion of their presentation. No other person attending the hearing may question a person making a presentation or interrupt the presentation of a participant.

Public hearings under part 15 are subject to FDA's guideline (21 CFR part 10, subpart C) on the policy and procedures for electronic media coverage of public administrative proceedings. Under § 10.205,

representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as required by § 15.30(b). Orders for copies of the transcript can be placed at the meeting or through the Dockets Management Branch (address above).

Any handicapped person requiring special accommodations in order to attend the hearing should direct those needs to the contact person listed above.

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing until December 29, 1995.

Dated: August 7, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95-20314 Filed 8-15-95; 8:45 am]

BILLING CODE 4160-01-F

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Meeting

Pursuant of Pub.L. 92-463, notice is hereby given of the meeting of the Center for Substance Abuse Treatment (CSAT) National Advisory Council in September 1995.

The meeting of the CSAT National Advisory Council will include a discussion of the mission and programs of the Center, policy issues and administrative, legislative, and program developments. The Council will also be performing a review of grant applications, contract proposals and procurement plans for Federal assistance; therefore a portion of this meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with 5 U.S.C. 552b(c)(3)(4) and (6) and 5 U.S.C. app. 2 10(d). Attendance by the public at the open portion of the meeting will be limited to space available. Public comments are welcome during the open session. Please communicate with the Contact person listed below for guidance.

A summary of the meeting and roster of council members may be obtained from: Ms. D. Winstead, Committee

Management Specialist, CSAT, Rockwall II Building, Suite 840, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-8448.

Substantive program information may be obtained from the contact whose name and telephone number is listed below.

Committee Name: The Center for Substance Abuse Treatment National Advisory Council.

Meeting Dates: September 14 and 15, 1995.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chase Room, Chevy Chase, Maryland 20815.

Type: Closed: September 14, 8:30 a.m.–10:30 a.m. Open: September 14, 10:30 a.m.–3:30 p.m. Open: September 15, 8:45 a.m.–2:15 p.m.

Contact: Marjorie Cashion, Rockwall II Building, Suite 840, Telephone: (301) 443-3821.

Dated: August 10, 1995.

Jeri Lipov,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

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BILLING CODE 4162-20-P

has been submitted to the Office of Management and Budget (OMN) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708-0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) an estimate of the total

number of hours heeded to prepare the information submission including number of respondents, frequency of response, and hours of response; (7) whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (8) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: August 10, 1995.

David S. Cristy,

Director, Information Resources Management Policy and Management Division.

Notice of Submission of Proposed Information Collection to OMB

Proposal: (1) Schedule of Subscribers and GNMA II Contractual Agreement and (2) Schedule of Subscribers Addendum for Construction Loan Certification.

Office: Government National Mortgage Association.

Description of the Need for the Information and Its Proposed Use: The forms are used to provide GNMA with a listing of subscribers and other information needed to prepare mortgage-backed securities. They are also used to provide the contractual agreement between the issuer and GNMA under the GNMA II program.

Form Number: HUD-11705 and 1735.

Respondents: Business or Other For-Profit and the Federal Government.

Reporting Burden:

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Administration

[Docket No. FR-3917-N-17]

Notice of Submission of Proposed Information Collection to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
HUD-11705	900		34		.17		5,202
HUD-1735	80		2		.17		27

Total Estimated Burden Hours: 5,229.

Status: Extension with changes.

Contact: Brenda Countee, HUD, (202) 708-2234; Joseph F. Lackey, Jr., OMB, (202) 395-7316.

Dated: August 10, 1995.

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BILLING CODE 4120-01-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, et seq.):

Applicant: William R. Hawkins, El Cajon, CA, PRT-805154.

The applicant requests a permit to import one sport-hunted bontebok (*Damaliscus pygargus dorcas*) culled

from the captive herd maintained by Mr. D.B. Pohl, "Tea Fountain", Republic of South Africa, for enhancement of the species.

Applicant: Thompson & Morgan, Inc., Jackson, NJ, PRT-805326. The applicant requests a permit to import and sell in interstate and foreign commerce artificially propagated seeds of Antioch dunes evening-primrose (*Oenothera deltoides howellii*) from Thompson & Morgan Ltd., United Kingdom, to enhance the propagation and survival of the species. This notification covers activities conducted by the applicant for a five year period.