(21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On March 19, 1996, Richard Hamer Associates, Inc., submitted a citizen petition (Docket No. 96P–0090/CP1) under 21 CFR 10.25(a), 10.30, and § 314.161(b), requesting that the agency determine whether testosterone propionate 2% ointment was withdrawn from sale for reasons of safety or effectiveness and, if the agency determines that the drug was not withdrawn from sale for reasons of safety or effectiveness, to relist the drug in the Orange Book. Testosterone propionate 2% ointment (Perandren Ointment) was the subject of approved NDA–0499 held by Ciba Pharmaceutical Co. In the Federal Register of September 23, 1971 (36 FR 18885), FDA withdrew approval of NDA– 0499 for Perandren Ointment based on the applicant's failure to submit required annual reports (section 505(e) of the act (21 U.S.C. 355(e)) and 21 CFR 314.80 and 314.81).

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that testosterone propionate 2% ointment was not withdrawn from sale for reasons of safety or effectiveness and will relist testosterone propionate 2% ointment in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to testosterone propionate 2% ointment may be approved by the agency.

Dated: November 27, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–31119 Filed 12–5–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0413]

Draft Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Germicides; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Germicides.'' The draft guidance provides specific directions to manufacturers regarding information and data that should be submitted to FDA in a premarket notification (510(k)) submission for a liquid chemical germicide. This draft guidance, dated April 26, 1995, replaces a previous version dated January 31, 1992.

DATES: Written comments by March 6, 1997.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6597 (toll free outside of MD 1–800–638–2041). Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 2085O, 301–443–8913.

SUPPLEMENTARY INFORMATION: FDA regulates the introduction of medical devices into interstate commerce. A person intending to market a liquid chemical germicide medical device must submit a premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) to FDA before introducing the device into interstate commerce. Regulations governing the general content and format of 510(k) submissions (21 CFR part 807) and other regulatory requirements are discussed in guidance documents available from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (address above). The intent of this draft guidance is to provide 510(k) applicants with specific directions regarding information and data that should be submitted to FDA in a 510(k) submission for a liquid chemical germicide medical device.

The effective use of chemical germicides is important in preventing nosocomial infections. Comprehensive, scientifically sound criteria for the evaluation of chemical germicides is essential to help ensure that these agents are safe and effective for their intended use when used according to their labeling. FDA recognizes the importance of providing applicants, and other interested parties, with the agency's 510(k) submission criteria for chemical germicides in order to facilitate assembly of necessary data, to maintain consistency of review, and to provide for a more efficient regulatory process. The draft guidance is predicated upon the legal principles of the 510(k) process. It also draws upon the longstanding regulatory and scientific basis for evaluation of germicides by the Federal government. It is a product of interactions with interested parties in industry, government, and academia as well as with infection control and other health care professionals.

This is a draft guidance document, and as such does not create or confer any rights for or on any person and does not operate to bind FDA or others; however, it does represent FDA's recommendations at this time. The draft guidance is not static and, thus, will be periodically revised to remain current with the state of the art in this fast changing area.

Interested persons may on or before March 6, 1997, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may

be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 20, 1996.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 96–31053 Filed 12–05–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

HRSA Competing Training Grant Application, Instructions and Related Regulations (OMB No. 0915–0060)—Extension and Revision

The Health Resources and Services Administration uses the information in the application to determine the eligibility of applicants for awards, to calculate the amount of each award, and to judge the relative merit of applications. This is a request for renewed clearance with several changes in the form. The form will be distributed electronically via the Internet, the budget will be negotiated for all years of the project period based on this application, and program-specific instructions will include greater standardization of content for the project summary and the detailed description of the project. Applications for selected programs must include data specified in statute. The statutory requirements are included in this clearance request.

Regulations which authorize the application form and other reporting, disclosure and recordkeeping requirements for various programs are also cleared in this package. No changes were made to the regulations.

The estimated annual burden for the application and associated regulations is as follows:

Requirement	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Basic application	1,787	1	61.25	109,454
Statutory reporting requirements	1,131	1	150	169,650
Regulatory requirements (see detailed table below):				
Reporting	45	1.7	1	75
Disclosure	168	1.1	3.4	622
Recordkeeping	86	1.2	1.7	168
Total	1,787			279,969

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Virginia Huth, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: November 27, 1996.

J. Henry Montes,

Associate Administrator for Policy Coordination.

[FR Doc. 96–31118 Filed 12–5–96; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4124–N–15]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: December 6, 1996.

FOR FURTHER INFORMATION CONTACT:

Mark Johnston, Department of Housing and Urban Development, Room 7256, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1226; TDD number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: November 26, 1996.

Jacquie M. Lawing,

Deputy Assistant Secretary for Economic Development.

[FR Doc. 96–30765 Filed 12–5–96; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UTU–73975]

Notice of Coal Lease Offering by Sealed Bid

U.S. Department of the Interior, Bureau of Land Management, Utah State Office, P.O. Box 45155, Salt Lake City, Utah 84145–0155. Notice is hereby given that at 1:00 p.m., December 18, 1996, certain coal resources in lands hereinafter described in Carbon County, Utah, will be offered for competitive lease by sealed bid of $100.00 per acre or more to the qualified bidder submitting the highest bonus bid in accordance with the provisions of the Mineral Leasing Act of 1920, as amended (41 Stat. 437). However, no bid will be accepted for less than fair