

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
170.35(c)(1)	1	1	1	2,614 (average)	2,614

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

FDA estimates that it may receive one GRAS petition annually. Although the burden varies with the type, size, and complexity of the petition submitted, GRAS petitions may involve analytical work, analysis of appropriate toxicological studies, and the work of drafting the petition itself. Since 1980, FDA has not received any petitions for affirmation of GRAS status under 21 CFR part 186—Indirect Food Substances Affirmed As Generally Recognized As Safe. Section 184.1(a) (21 CFR 184.1(a)) affirms the use of those substances affirmed as GRAS in 21 CFR part 184—Direct Food Substances Affirmed As Generally Recognized As Safe, for use as indirect food ingredients.

Dated: September 19, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–24479 Filed 9–22–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1328]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Latex Condoms; User Labeling; Expiration Dating

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 October 25, 2000.

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: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, 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.

Latex Condoms; User Labeling; Expiration Dating—21 CFR 801.435 (OMB Control No. 0910–0352)—Extension

Sections 502(a), 519, 701, and 704 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(a), 360(i), 371, and 374) establish the statutory authority to collect information under this regulation. Section 519 of the act describes recordkeeping, section 502(a) describes misbranding, section 704 describes authority for inspections, and section 701 describes general administrative procedures and regulations and hearings.

To protect the public health and minimize the risk of device failure, latex condoms are required to be labeled with an expiration date, which must be

supported by data from quality control tests demonstrating physical and mechanical integrity of three random lots of the same product that were stored under accelerated and real time conditions (§ 801.435 (21 CFR 801.435)).

The recording of shelf life testing by condom manufacturers is used to support the expiration dating on the labeling of latex condoms. Information concerning latex shelf life is necessary to allow lay users to use these products safely by avoiding use of products that may have degraded. Degradation of latex film products like latex condoms occurs when latex is exposed to various types of environmental conditions normally experienced in product use, shipment, or storage situations. The effectiveness of latex condoms as a barrier to the transmission of infectious agents is dependent upon the integrity of the latex material. The information and records generated by condom manufacturers under this regulation will be used to establish an expiration date that will inform consumers when the product should no longer be used.

Section 510(h) of the act (21 U.S.C. 360(h)) requires that condom manufacturers as device manufacturers be inspected at least once in a 2-year period. During that inspection, FDA inspectors will review the test records used to support the expiration date in order to ensure that the expiration date is accurate. The respondents to this collection of information are domestic and foreign condom manufacturers.

In the **Federal Register** of June 23, 2000 (65 FR 39150), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
801.435	45	1	45	96	4,320

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

The number of domestic establishments was estimated by reviewing the FDA data base of

registered medical device manufacturers to arrive at 5 domestic and 40 foreign condom manufacturers. Based upon

conversations with condom manufacturers, FDA field personnel, and comments received from the public

during this collections initial approval, FDA determined the number hours to complete labeling and testing of condoms to be 96 hours per respondent.

Dated: September 19, 2000.

William K. Hubbard,

*Senior Associate Commissioner for Policy,
Planning, and Legislation.*

[FR Doc. 00-24480 Filed 9-22-00; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Application for Endangered Species Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Receipt of Application for Endangered Species Permit.

SUMMARY: The following applicants have applied for permits 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.*).

If you wish to comment, you may submit comments by any one of several methods. You may mail comments to the Service's Regional Office (see **ADDRESSES**). You may also comment via the internet to

"victoria_davis@fws.gov". Please submit comments over the internet as an ASCII file avoiding the use of special characters and any form of encryption. Please also include your name and return address in your internet message. If you do not receive a confirmation from the Service that we have received your internet message, contact us directly at either telephone number listed below (see **FURTHER INFORMATION**). Finally, you may hand deliver comments to either Service office listed below (see **ADDRESSES**). Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the administrative record. We will honor such requests to the extent allowable by law. There may also be other circumstances in which we would withhold from the administrative record a respondent's identity, as allowable by law. If you wish us to withhold your name and address, you must state this prominently at the beginning of your comments. We will not, however, consider anonymous comments. We will make all submissions from

organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

DATES: Written data or comments on these applications must be received, at the address given below, by October 25, 2000.

ADDRESSES: Documents and other information submitted with these applications are available for review, *subject to the requirements of the Privacy Act and Freedom of Information Act*, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (Attn: Victoria Davis, Permit Biologist). Telephone: 404/679-4176; Facsimile: 404/679-7081.

FOR FURTHER INFORMATION CONTACT: Victoria Davis, Telephone: 404/679-4176; Facsimile: 404/679-7081.

SUPPLEMENTARY INFORMATION:

Applicant: Brian R. Roh, Burns & McDonnell, Kansas City, Missouri, TE033460-0.

The applicant requests authorization to take (capture, identify, and release) the endangered American Burying Beetle, *Nicrophorus americanus*, around Lake Fort Smith and Lake Shepherd Springs in Crawford County, Arkansas for the purpose of enhancement of survival of the species.

Applicant: Felicia J. Sanders, Tucker, Georgia, TE033469-0.

The applicant requests authorization to take (capture, band, install inserts, and harass during nest monitoring and construction of artificial cavities) the endangered red-cockaded woodpecker, *Picoides borealis*, throughout the species range, for the purpose of enhancement of survival of the species.

Dated: September 18, 2000.

Sam D. Hamilton,

Regional Director.

[FR Doc. 00-24533 Filed 9-22-00; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT-925-2810-XU-241E]

Notice of Rescindment of Special Fire Restrictions and Closures in the Billings, Miles City, Malta and Lewistown Field Offices; MT

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Pursuant to 43 Code of Federal Regulations 9212.2, the prohibitions listed in Order No. MT-00-12, MT-00-09 (Stillwater, Carbon and Sweetgrass counties), MT-00-05 applicable to Bureau of Land Management lands administered by the Billings, Miles City, Malta, and Lewistown Field Offices, dated September 12, 2000, September 5, 2000 and August 11, 2000, will be terminated at 12:01 a.m. Friday, September 22, 2000.

DATES: Restrictions are terminated at 12:01 a.m. on Friday, September 22, 2000.

ADDRESSES: Comments should be sent to BLM Montana State Director, Attention: Pat Mullaney, P.O. Box 36800, Billings, Montana 59107-6800.

FOR FURTHER INFORMATION CONTACT: Pat Mullaney, Fire Management Specialist, 406-896-2915.

Dated: September 20, 2000.

Mat Millenbach,

State Director.

[FR Doc. 00-24623 Filed 9-21-00; 2:08 pm]

BILLING CODE 4310-SS-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT-930-07-1320-00]

Release of Coal Exploration License Data, UTU-48608

ACTION: Notice of determination to allow public access to data from coal exploration license UTU-48608.

SUMMARY: BLM regulations at 43 CFR 2.22 and 3410.4(b) provide that data obtained under an exploration license will be kept confidential until the lands have been leased or BLM determines that public access to the data would not damage the competitive position of the licensee, whichever comes first. Coal exploration License UTU-48068 was issued to Royal Land Company on August 4, 1981. Exploration on this license included drilling 15 holes in the vicinity of North Horn Mountain, Emery County, Utah. The lands covered by this license were offered for lease on May 29, 1982, and no bids were received. Since May 29, 1982, no application has been made for a lease on these lands in accordance with 43 CFR 3425. The coal interests in part of the lands contained within UTU-48068 were transferred to the State of Utah pursuant to the provisions of the Utah Schools and Lands Exchange Act of 1998.