

support state and local ground water quality protection mechanisms.

## VI. Summary and Discussion of Public Comments

In response to the Public Notice, EPA received 6 comments endorsing Sole Source Aquifer designation. No additional questions were raised during the comment period. No comments objecting to designation were received during any portion of public participation process.

During the public comment period no data were presented to EPA regarding aquifer characteristics, boundary delineation or potential errors of fact presented in the petition.

## VII. Economic and Regulatory Impact

Pursuant to the provisions of the Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), I hereby certify that this designation will not have a significant impact on a substantial number of small entities. For purposes of this Certification, "small entity" shall have the same meaning as given in section 601 of the RFA. This action is only applicable to projects with the potential to impact the Castle Valley Aquifer System Sole Source Aquifer as designated.

The only affected entities will be those businesses, organizations or governmental jurisdictions that request federal financial assistance for projects which have the potential for contaminating the Sole Source Aquifer so as to create a significant hazard to public health. EPA does not expect to be reviewing small isolated commitments of financial assistance on an individual basis, unless a cumulative adverse impact on the aquifer is anticipated or brought to the Agencies attention; accordingly, the number of affected small entities will be minimal.

For those small entities that are subject to review, the impact of today's action will not be significant. Many projects subject to this review will be preceded by a ground water impact assessment required pursuant to other federal laws, such as the National Environmental Policy Act (NEPA) as amended 42 U.S.C. 4321, *et seq.* Integration of those related review procedures with sole source aquifer review will allow EPA and other federal agencies to avoid delay or duplication of effort in approving financial assistance, thus minimizing any adverse effects on those small entities which are affected. Finally, today's action does not prevent grants of federal financial assistance which may be available to any affected small entity in order to pay for the

redesign of the project to assure protection of the aquifer.

Under Executive Order 12866, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This regulation is not major because it will not have an annual effect of \$100 million or more on the economy, will not cause any major increase in costs or prices and will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States enterprises to compete in domestic or export markets. Today's action only affects the Castle Valley Aquifer System in Grand County, Utah. It provides an additional review of ground water protection measures, incorporating state and local measures whenever possible, for only those projects which request federal financial assistance.

Dated: July 26, 2001.

**Jack W. McGraw,**

*Acting Regional Administrator, Region VIII.*

[FR Doc. 01-19566 Filed 8-3-01; 8:45 am]

**BILLING CODE 6560-50-P**

## GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-0007]

### Submission for OMB Review; Comment Request Entitled Contractor's Qualifications and Financial Information

**AGENCY:** Office of the Chief Financial Officer (B), GSA.

**ACTION:** Notice of request for public comments regarding extension of a currently approved OMB clearance (3090-0007).

**SUMMARY:** Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Office of Acquisition Policy has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning Contractor's Qualifications and Financial Information.

**DATES:** Comment Due Date: October 5, 2001.

**FOR FURTHER INFORMATION CONTACT:** Michael J. Kosar, Office of the Chief Financial Officer, GSA (202) 501-2029.

**ADDRESSES:** Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, should be submitted to: Edward

Springer, GSA Desk Officer, OMB, Room 10236, NEOB, Washington, DC 20503, and a copy to Stephanie Morris, General Services Administration (MVP), 1800 F Street NW., Room 4035 Washington, DC 20405

## SUPPLEMENTARY INFORMATION:

### A. Purpose

The General Services Administration is requesting the Office of Management and Budget (OMB) to extend information collection, 3090-0007, concerning Contractor's Qualifications and Financial Information. This form is used to determine the financial capability of prospective contractors as to whether they meet the financial responsibility standards in accordance with the Federal Acquisition Regulation (FAR) and the General Services Administration Acquisition Regulation (GSAR).

### B. Annual Reporting Burden

Respondents: 2,306.

Annual responses: 2,767.

Average hours per response: 2.5.

Burden hours: 6,917.

*Copy of Proposal:* A copy of this proposal may be obtained from the General Services Administration, Acquisition Policy Division (MVP), Room 4035, 1800 F Street NW., Washington, DC 20405, or by telephoning (202) 501-4744, or by faxing your request to (202) 501-4067. Please cite OMB Control No. 3090-0007, Contractor's Qualifications and Financial Information, in all correspondence.

Dated: July 27, 2001.

**David A. Drabkin,**

*Deputy Associate Administrator, Office of Acquisition Policy.*

[FR Doc. 01-19516 Filed 8-3-01; 8:45 am]

**BILLING CODE 6820-61-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0317]

### Mylan Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 66 Abbreviated New Drug Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of 66 abbreviated new drug applications (ANDAs). The holders of the applications notified the agency in

writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Effective September 5, 2001.

**FOR FURTHER INFORMATION CONTACT:**  
Florine P. Purdie, Center for Drug

Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** The holders of the applications listed in the table in this document have informed

FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

ANDA No.	Drug	Applicant
61-755	Ampicillin Capsules USP, 250 milligrams (mg) and 500 mg.	Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504.
62-090	Amoxicillin for Oral Suspension USP, 125 mg/5 milliliters (mL) and 250 mg/5 mL.	Do.
62-928	Clindamycin Phosphate Injection USP, 150 mg/mL.	AstraZeneca, 725 Chesterbrook Blvd., Wayne, PA 19087-5677.
63-167	Amikacin Sulfate Injection USP, 50 mg (base)/mL.	Do.
63-169	Amikacin Sulfate Injection USP, 250 mg (base)/mL.	Do.
70-095	Furosemide Injection USP, 10 mg/mL.	Do.
70-096	Furosemide Injection USP, 10 mg/mL.	Do.
70-529	Indomethacin Capsules USP, 25 mg.	Watson Laboratories, Inc., 311 Bonnie Circle, Corona, CA 92880.
70-530	Indomethacin Capsules USP, 50 mg.	Do.
70-645	Metoclopramide Tablets, 10 mg.	Do.
71-920	Methyldopa and Hydrochlorothiazide Tablets USP, 250 mg/15 mg.	Do.
71-921	Methyldopa and Hydrochlorothiazide Tablets USP, 250 mg/25 mg.	Do.
71-922	Methyldopa and Hydrochlorothiazide Tablets USP, 500 mg/30 mg.	Do.
71-923	Methyldopa and Hydrochlorothiazide Tablets USP, 500 mg/50 mg.	Do.
72-023	Metaproterenol Sulfate Syrup USP, 10 mg/5 mL.	Muro Pharmaceuticals, Inc., 890 East St., Tewksbury, MA 01876.
72-081	Naloxone Hydrochloride (HCl) Injection USP, 0.02 mg/mL.	AstraZeneca.
72-086	Naloxone HCl Injection USP, 0.4 mg/mL.	Do.
72-091	Naloxone HCl Injection USP, 1 mg/mL.	Do.
72-165	Fenopropfen Tablets USP, 600 mg.	Watson Laboratories, Inc.
72-293	Fenopropfen Capsules USP, 300 mg.	Do.
72-294	Fenopropfen Capsules USP, 200 mg.	Do.
72-372	Duphalac (Lactulose Solution USP), 10 grams/15 mL.	Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062.
73-062	Loperamide HCl Oral Solution, 1 mg/5 mL.	Watson Laboratories, Inc.
73-106	Acetaminophen Suppositories USP, 120 mg.	Able Laboratories, Inc., 6 Hollywood Ct., South Plainfield, NJ 07080.
73-107	Acetaminophen Suppositories USP, 325 mg.	Do.
73-108	Acetaminophen Suppositories USP, 650 mg.	Do.
73-120	Albuterol Tablets USP, 2 mg.	Medeva Pharmaceuticals, Inc., 3501 West Garry Ave., Santa Ana, CA 92704.
73-121	Albuterol Tablets USP, 4 mg.	Do.
73-165	Albuterol Sulfate Syrup, 2 mg/5 mL.	Watson Laboratories, Inc.
73-381	Carbidopa and Levodopa Tablets USP, 10 mg/100 mg.	Do.
73-382	Carbidopa and Levodopa Tablets USP, 25 mg/100 mg.	Do.
73-383	Carbidopa and Levodopa Tablets USP, 25 mg/250 mg.	Do.
73-651	Piroxicam Capsules USP, 10 mg and 20 mg.	Roxane Laboratories, Inc., P.O. Box 16532, Columbus, OH 43216.
74-156	Gemfibrozil Tablets USP, 600 mg.	Watson Laboratories, Inc.
74-199	Alprazolam Tablets USP, 0.25 mg, 0.5 mg, and 1 mg.	Roxane Laboratories, Inc.
74-319	Naproxen Sodium Tablets USP.	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.
74-570	Acyclovir Capsules USP, 200 mg.	Roxane Laboratories, Inc.
74-897	Acyclovir Sodium for Injection, USP.	Apothecon, Inc., P.O. Box 4500, Princeton, NJ 08543.
74-972	Cimetidine Tablets USP, 100 mg.	L. Perrigo Co., 515 Eastern Ave., Allegan, MI 49010.
80-109	Sulfisoxazole Tablets USP, 500 mg.	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
80-782	Prednisone Tablets USP, 5 mg.	Do.
83-080	Aquasol A (Vitamin A Capsules USP).	AstraZeneca.
83-857	Estratab Esterified Estrogens Tablets USP, 2.5 mg.	Solvay Pharmaceuticals, Inc.
84-574	Aminophylline Tablets, 100 mg.	Impax Laboratories, Inc.
84-576	Aminophylline Tablets, 200 mg.	Do.
84-922	Hydralazine HCl Tablets USP, 25 mg.	Do.
85-171	Glutethimide Tablets USP, 500 mg.	Medeva Pharmaceuticals, Inc.
85-264	Bronkodyl (Theophylline Capsules USP), 100 mg and 200 mg.	Sanofi-Synthelabo, Inc., 90 Park Ave., 6th Fl., New York, NY 10016.
85-376	Dexamethasone Tablets USP, 0.75 mg.	Impax Laboratories, Inc.

ANDA No.	Drug	Applicant
85-544 .....	Diethylpropion HCl Tablets USP, 25 mg. ....	Medeva Pharmaceuticals, Inc.
85-864 .....	Amitriptyline HCl Tablets USP, 10 mg. ....	Do.
85-935 .....	Amitriptyline HCl Tablets USP, 25 mg. ....	Do.
85-936 .....	Amitriptyline HCl Tablets USP, 50 mg. ....	Do.
86-335 .....	Amitriptyline HCl Tablets USP, 150 mg. ....	Do.
86-336 .....	Amitriptyline HCl Tablets USP, 100 mg. ....	Do.
86-337 .....	Amitriptyline HCl Tablets USP, 75 mg. ....	Do.
87-156 .....	Fluonid (Fluocinolone Acetonide) Cream, 0.025% .....	Allergan, 2525 Dupont Dr., P.O. Box 19534, Irvine, CA 92623.
87-157 .....	Fluonid (Fluocinolone Acetonide) Ointment, 0.025% .....	Do.
88-075 .....	Amitriptyline HCl Tablets, 10 mg. ....	Purepac Pharmaceutical Co.
88-076 .....	Amitriptyline HCl Tablets, 25 mg. ....	Do.
88-077 .....	Amitriptyline HCl Tablets, 50 mg. ....	Do.
88-078 .....	Amitriptyline HCl Tablets, 75 mg. ....	Do.
88-079 .....	Amitriptyline HCl Tablets, 100 mg. ....	Do.
88-215 .....	Penecort (Hydrocortisone) Gel, 1%. ....	Allergan
88-217 .....	Penecort (Hydrocortisone) Ointment, 2.5%. ....	Do.
89-495 .....	Hydrocortisone Lotion USP, 1%. ....	Beta Dermaceuticals, Inc., P.O. Box 691106, San Antonio, TX 78269.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective September 5, 2001.

Dated: July 24, 2001.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 01-19509 Filed 8-3-01; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF THE INTERIOR**

**Bureau of Land Management**

[WY-920-09-1320-EM, WYW153943]

**Coal Lease Exploration License, WY**

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of invitation for coal exploration license.

**SUMMARY:** Pursuant to section 2(b) of the Mineral Leasing Act of 1920, as amended by section 4 of the Federal Coal Leasing Amendments Act of 1976, 90 Stat. 1083, 30 U.S.A. 201 (b), and to the regulations adopted as 43 CFR 3410, all interested parties are hereby invited to participate with Triton Coal Company, LLC on a pro rata cost sharing basis in its program for the exploration of coal deposits owned by the United States of America in the following-described lands in Campbell County, WY:

*T. 52 N., R. 72 W., 6th P.M., Wyoming*  
 Sec. 8: Lots 1-12;

Sec. 9: Lots 3-6 and 11-14.  
 Containing 811.81 acres, more or less.

All of the coal in the above-described land consists of unleased Federal coal within the Powder River Basin Known Recoverable Coal Resource Area. The purpose of the exploration program is to obtain overburden geochemistry, structural information, and coal quality data on the Anderson and Canyon coal seams.

**ADDRESSES:** The proposed exploration program is fully described and will be conducted pursuant to an exploration plan to be approved by the Bureau of Land Management (BLM). Copies of the exploration plan are available for review during normal business hours in the following offices (serialized under number WYW153943): BLM, Wyoming State Office, 5353 Yellowstone Road, P.O. Box 1828, Cheyenne, WY 82003; and, BLM, Casper Field Office, 2987 Prospector Drive, Casper, WY 82604.

**SUPPLEMENTARY INFORMATION:** This notice of invitation will be published in The News-Record of Gillette, WY, once each week for two consecutive weeks, beginning the week of Aug. 6, 2001, and in the **Federal Register**. Any party electing to participate in this exploration program must send written notice to both the BLM and Triton Coal Company, LLC, no later than thirty days after publication of this invitation in the **Federal Register**. The written notice should be sent to the following addresses: Triton Coal Company, LLC, Attn: Steve Salonek, P.O. Box 3027, Gillette, WY 82717-3027, and the BLM, Wyoming State Office, Minerals and Lands Authorization Group, Attn: Julie Weaver, P.O. Box 1828, Cheyenne, WY 82003-1828.

The foregoing is published in the **Federal Register** pursuant to 43 CFR 3410.2-1(c)(1).

Dated: July 20, 2001.

**Phillip C. Perlewitz,**

*Chief, Branch of Solid Minerals.*

[FR Doc. 01-19212 Filed 8-3-01; 8:45 am]

**BILLING CODE 4310-22-P**

**DEPARTMENT OF THE INTERIOR**

**Bureau of Land Management**

[WY-060-1320-EL, WYW146744]

**Federal Coal Lease Application**

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of availability of a Final Environmental Impact Statement on the North Jacobs Ranch Federal Coal Lease Application in the Decertified Powder River Federal Coal Production Region, Wyoming.

**SUMMARY:** Pursuant to the National Environmental Policy Act (NEPA) and implementing regulations and other applicable statutes, the Bureau of Land Management (BLM) announces the availability of a Final Environmental Impact Statement (FEIS) for the North Jacobs Ranch Coal Lease Application, BLM serial number WYW146744, in the Wyoming Powder River Basin. The FEIS analyzes the impacts of issuing a Federal coal lease for the proposed North Jacobs Ranch Federal coal tract. The North Jacobs Ranch tract is being considered for sale as a result of a coal lease application received from Jacobs Ranch Coal Company (JRCC) on October 2, 1998. JRCC is a subsidiary of Kennecott Energy Company. The tract as applied for includes about 4,821.19 acres containing approximately 533