1. ANDA 87–465; Methandrostenolone 2.5 milligrams (mg) tablets; Bolar Pharmaceuticals Co., Inc., 130 Lincoln St., Copiague, NY 11726.

2. ANDA 87–466; Methandrostenolone 5 mg tablets; Bolar Pharmaceutical Co., Inc.

Bolar has since withdrawn its hearing request. Accordingly, FDA is now withdrawing approval of ANDA's 87–465 and 87–466 for methandrostenolone tablets.

The Director of the Center for Drugs and Biologics, under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052–1053 as amended (21 U.S.C. 355)) and under the authority delegated to him (21 CFR 5.82) finds that, on the basis of new information before him with respect to the products, evaluated together with the evidence available to him when the applications were approved, there is a lack of substantial evidence that the products will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

Therefore, pursuant to the foregoing finding, approval of ANDA's 87–465 and 87–466 and all the amendments and supplements thereto is withdrawn effective January 13, 1986. Shipment in interstate commerce of these products will then be unlawful.

Dated: December 6, 1985.

Paul Parkman,

Acting Director Center for Drugs and Biologics

[FR Doc. 85–29521 Filed 12–12–85; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 76N–0256; DESI 9149]

Drugs for Human Use; Trifluoperazine Hydrochloride; Request for Revised Labeling

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces that trifluoperazine hydrochloride is safe and effective for the short-term treatment of generalized non-psychotic anxiety and requests that manufacturers of the drug include this indication in the labeling for their products. The agency also provides the acceptable wording for such labeling revisions.

EFFECTIVE DATE: This notice is effective on December 13, 1985.

ADDRESSES: Communications in response to this notice should be identified with reference number DESI 9149 and sent to the appropriate office named below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Supplements to full new drug applications (identify with NDA number): Division of Neuropharmacological Drug Products (HFN–120), Center for Drugs and Biologics.

Original abbreviated new drug applications and supplements thereto (identify as such): Division of Generic Drugs (HFN–230), Center for Drugs and Biologics.

Requests for opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFN–310), Center for Drugs and Biologics.

FOR FURTHER INFORMATION CONTACT: John H. Hazard, Jr., Center for Drugs and Biologics (HFN–366), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3650.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 4, 1982 (47 FR 24445), FDA announced its conclusions concerning the effectiveness of trifluoperazine drug products. The agency concluded that the drug was effective only for the indication, "For use in the management of all manifestations of psychotic disorders." The indication, "To control excessive anxiety, tension, and agitation as seen in neuroses or associated with somatic conditions," was reclassified to lacking substantial evidence of effectiveness, and the agency offered an opportunity for a hearing on the proposal to withdraw approval of the parts of the new drug application (NDA) providing for that indication.

SmithKline Beckman Corporation (SKF), sponsor of the NDA listed below, requested a hearing. The firm later withdrew its hearing request and conducted clinical studies on the effectiveness of the drug for the non-psychotic anxiety indication. The Director of the Center for Drugs and Biologics has evaluated the data submitted to support the product's effectiveness for that indication and announces his conclusion herein.

I. The Drug Products

NDA 11–552; Stelazine containing trifluoperazine hydrochloride, in tablets of 1, 2, 5, or 10 milligrams (mg); in 10 mg per milliliter (mL) concentrated solution; and in 2 mg/mL injectable solution; SmithKline Beckman Corp., 1500 Spring Garden St., Philadelphia, PA 19101.

Under the conditions for approval and marketing set forth in the June 1982 notice, FDA also has approved the following abbreviated new drug applications (ANDA's):

1. ANDA 85–785; 1 mg base; Cord Pharmaceuticals, 2599 W. Midway Blvd., Broomfield, CO 80020.

2. ANDA 85–786; 2 mg base; Cord.

3. ANDA 85–787; 10 mg base/mL; Cord.

4. ANDA 85–788; 10 mg base; Cord.

5. ANDA 85–789; 5 mg base; Cord.

6. ANDA 85–328; 5 mg base; Zenith Laboratories, Inc., 140 LeGrand Ave., Northvale, NJ 07647.

7. ANDA 87–612; 1 mg base; Zenith.

8. ANDA 87–613; 2 mg base; Zenith.

9. ANDA 87–614; 10 mg base; Zenith.

10. ANDA 88–143; 10 mg base/mL; Bay Laboratories, Inc., 3654 West Jarvis, Skokie, IL 60076.

11. ANDA 88–967; 1 mg base; Duramed Pharmaceuticals Inc.,5040 Lester Rd., Cincinnati, OH 45213.

12. ANDA 88–968; 2 mg base; Duramed.

13. ANDA 88–969; 5 mg base; Duramed.

14. ANDA 88–970; 10 mg base; Duramed.

II. Evidence of Effectiveness

SKF conducted a four-week, double-blind, parallel multi-center study comparing Stelazine (2–6 mg daily) with an identical placebo in 415 patients. Eleven independent investigators participated in the study. The investigators were randomized by FDA into two subgroups before SKF analyzed the data. The results reveal that Stelazine produced more improvement than placebo in key measures of anxiety, ranging from 30 to 53 percent for the Stelazine patients and from 19 to 38 percent for the placebo patients. Those improvements are statistically significant differences between Stelazine and placebo. No unusually serious adverse effects occurred during the trial, and there was no apparent difference between Stelazine and placebo in the incidence of abnormal clinical laboratory values. Thus the Director concludes that the drug is safe and effective for the short-term treatment of generalized non-psychotic anxiety.

III. Request for Labeling Revision

Because the Director has concluded that trifluoperazine is safe and effective for non-psychotic anxiety, the manufacturers listed above are requested to add this indication to their products' labeling. To market a trifluoperazine product for this additional indication, approval of a supplement providing for revised labeling in accordance with this notice must be obtained. The Director also requests that any person seeking

approval of an ANDA for a trifluoperazine product as provided in the June 4, 1982 notice and earlier notices add the indication for non-psychotic anxiety to the proposed labeling.

The INDICATIONS section of the labeling should be revised to include the following information (editorially adapted to a specific product's labeling as appropriate):

Stelazine (trifluoperazine) is effective for the short-term treatment of generalized non-psychotic anxiety. However, Stelazine is not the first drug to be used in therapy for most patients with non-psychotic anxiety because certain risks associated with its use are not shared by common alternative treatments (i.e., benzodiazepines).

When used in the treatment of non-psychotic anxiety, Stelazine should not be administered at doses of more than 6 mg per day for longer than 12 weeks because the use of Stelazine at higher doses or for longer intervals may create persistent tardive dyskinesia that may prove irreversible (see WARNINGS section.

The effectiveness of Stelazine as a treatment for non-psychotic anxilty was established in a four-week clinical multi-center study of outpatients with generalized anxiety disorder (DSM III). This evidence does not predict that Stelazine will be useful in patients with other non-psychotic conditions in which anxiety, or signs that mimic anxiety, are found (i.e., physical illness, organic mental conditions, agitated depression, character pathologies, etc.).

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050–1053, as amended (21 U.S.C. 352, 355)) and under authority delegated to the Director of the Center for Drugs and Biologics (21 CFR 5.70).

Dated: December 6, 1985.

Paul Parkman,

Acting Director, Center for Drugs and Biologics

[FR Doc. 85–29523 Filed 12–12–85; 8:45 am]

BILLING CODE 4160-01-M

Health Resources and Services Administration

Task Force on Organ Transplantation; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following national advisory body scheduled to meet during the month of January 1986:

Name: Task Force on Organ Transplantation.

Date and Time: January 9–10, 1986 8:30 a.m.

Place: Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, Virginia 22203.

The entire meeting is open to the public.

Purpose: the Task Force on Organ Transplantation is required to conduct comprehensive examinations of the medical, legal, ethical economic, and social issues presented by human organ procurement and transplantation; including and assessment of immunosuppressive medications used to prevent organ rejection in transplant patients. Reports on these issues are required to be submitted to the Department of Health and Human Services and the Congress later this year.

Agenda: Discussion of (1) the feasibility of establishing a national registry of human organ donors; (2) proposed recommendations for assuring equitable access by patients to organ transplantation; (3) proposed recommendations concerning the designation of transplant centers and reimbursement for extrarenal transplants; (4) proposed recommendations to improve the organ procurement system; and (5) implementation priorities for organ procurement organization grant program.

Public comment will begin at 4:30 p.m. on January 9. Anyone wishing to make a statement, please notify Linda D. Sheaffer, Executive Director, so that these may be scheduled.

Anyone wishing to obtain a roster of members, minutes of meetings, or other relevant information should write to or contract Ms. Linda D. Sheaffer, Executive Director, Office of Organ Procurement and Transplantation, Office of the Administrator, Health Resources and Services Administration, Room 17–60, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443–5911.

Agenda items are subject to change as priorities dictate.

Dated: December 10, 1985.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 85–29578 Filed 12–12–85; 8:45 am]

BILLING CODE 4160-16-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered Species Convention; Foreign Law Notifications; Bolivia.

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Information No. 8.

This is a Schedule I notice: wildlife subject to this notice is subject to detention, refusal of clearance, seizure, and forfeiture if imported into the United States.

Subject: Bolivia—Ban on live wildlife exports.

Source of Foreign Law Information: Announcement by the Bolivian Management Authority, 5 COP CITES, April 22–May 3, 1985, confirmed by copy of Ministerial Resolution No. 226–85 dated August 2, 1985, forwarded by the Department of State October 9, 1985.

Action: By NOI No. 3 (50 FR 34016) published August 22, 1985, the Service notified the public that the Bolivian government had imposed a ban upon exports of live wildlife from that country and that no imports of live wildlife would be allowed into the United States from Bolivia. The Bolivian government has extended its ban until August 1, 1986. The Service, therefore, will not allow any imports of live wildlife from Bolivia, or which designate Bolivia as country of origin, and exported after May 1, 1984.

DATES: Effective date: December 13, 1985. Expiration date: August 1, 1986.

FOR FURTHER INFORMATION CONTACT: Kathleen King, Division of Law Enforcement, U.S. Fish and Wildlife Service, P.O. Box 28006, Washington, DC 20005, Telephone: 202/343–9242.

Dated: December 9, 1985.

Ronald E. Lamberton,

Acting Deputy Director.

[FR Doc. 85–29524 Filed 12–12–85; 8:45 am]

BILLING CODE 4310-55-M

Bureau of Land Management

Buffalo Resource Area, Casper District, WY; Availability of the Resource Management Plan and Record of Decision

AGENCY: Bureau of Land Management, Interior.

ACTION: Public notice that the Wyoming State Director has approved, in a record of decision (ROD), the resource management plan (RMP) for the Buffalo Resource Area.

SUMMARY: The approved plan will be implemented on about 800,000 acres of BLM-administered public surface and 4.73 million acres of mineral estate. The ROD adopted the proposed plan that was presented in the final environmental impact statement (EIS). This plan will guide future management in the Resource Area.

Location of Document: The ROD and associated draft and final EIS's are

available to the public upon request to: Glenn Bessinger, Area Manager, Buffalo Resource Area, Bureau of Land Management, 300 Spruce Street, Buffalo, WY 82834, Phone: (307) 684-5586.

Public Participation: The public was invited to participate in the RMP in issue identification and development of planning criteria during a 90-day comment period allowed on the draft EIS and at a public hearing held during the comment period. No protests were received during the 30-day protest period allowed after publication of the final EIS.

SUPPLEMENTARY INFORMATION: Four management alternatives were developed during the planning process and were analyzed in the EIS. The alternatives were "No Action" (or continuation of existing management), an alternative that attempted to balance land use demands and resource availability with environmental integrity, an alternative emphasizing economic production, and an alternative that emphasized environmental protection. The balanced alternative was selected for the proposed management plan in the final EIS and is the plan approved by this ROD. It presents a cost-effective plan that best responds to the issues in a multiple use-sustained yield framework. It provides for a variety of resource uses and protects the environment through mitigation of impacts. The approved plan includes all practicable mitigation. After implementation, other site-specific mitigation may be required to address impacts from specific land use proposals.

Three wilderness study areas (WSA's) will continue to be managed under the interim wilderness guidelines until Congress determines whether or not they will be designated as wilderness areas. A wilderness study report, which recommends that these WSA's not be designated as wilderness, will be sent to the Secretary of the Interior. Should Congress decide to adopt these recommendations, the WSA's will be managed as outlined in the RMP. Should Congress decide to designate one or more of the WSA's as wilderness, the RMP will be modified as necessary and the areas will be managed accordingly.

Progress toward accomplishing goals and objectives in the plan will be monitored. The plan will be maintained to keep it current. It may be amended or a new plan developed it management goals and objectives change.

Dated: December 4, 1985.

Hillary A. Oden,

State Director.

[FR Doc. 85-29426 Filed 12-12-85; 8:45 am]

BILLING CODE 4310-22-M

National Park Service

Delta Region Preservation Commission; Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act that a meeting of the Delta Region Preservation Commission will be held at 7:30 p.m., CST, on January 7, 1986, at the Jefferson Parish East Bank Council Chamber, 3330 North Causeway Boulevard, Metairie, Louisiana.

The Delta Region Preservation Commission was established pursuant to Pub. L. 95-256, section 907(a) to advice the Secretary of the Interior in the selection of sites for inclusion in Jean Lafitte National Historical Park, and in the implementation and development of a general management plan and of a comprehensive interpretative program of the natural, historic, and cultural resources of the Region.

The matters to be discussed at this meeting include:

—Prairie Producing Corporation
—Land Acquisition Program
—General Management Plan Amendment—Chalmette
—Cooperative Agreements—Thibodaux and Lafayette

The meeting will be open to the public. However, facilities and space for accommodating members of the public are limited, and persons will be accommodated on a first-come, first-serve basis. Any member of the Public may file a written statement concerning the matters to be discussed with the Superintendent, Jean Lafitte National Historical Park.

Persons wishing further information concerning this meeting, or who wish to submit written statements may contact James Isenogle, Superintendent, Jean Lafitte National Historical Park, U.S. Customs House, 423 Canal Street, Room 206, New Orleans, Louisiana 70130, telephone 504/589-3882. Minutes of the meeting will be available for public inspection four weeks after the meeting at the office of Jean Lafitte National Historical Park.

Dated: December 4, 1985.

Robert I. Kerr,

Regional Director, Southwest Region.

[FR Doc. 85-29555 Filed 12-12-85; 8:45 am]

BILLING CODE 4310-70-M

INTERSTATE COMMERCE COMMISSION

[Docket No. AB-52 (Sub-No. 42X)]

The Atchison, Topeka and Santa Fe Railway Co.; Abandonment Exemption in Alameda County, CA

Applicant has filed a notice of exemption under 49 CFR 1152 Part Subpart F—*Exempt Abandonments* to abandon its .57-mile line of railroad between milepost 10.27 and milepost 9.7 in the city of Oakland, Alameda County, CA.

Applicant has certified (1) that no local traffic has moved over the line for at least 2 years and that overhead traffic is not moved over the line, and (2) that no formal complaint filed by a user of rail service on the line (or by a State or local governmental entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or any U.S. District Court, or has been decided in favor of the complainant within the 2-year period. The appropriate State agency has been notified in writing at least 10 days prior to the filing of this notice.

As a condition to use of this exemption, any employee affected by the abandonment shall be protected pursuant to *Oregon Short Line R. Co.-Abandonment-Goshen*, 360 I.C.C. 91 (1979).

The exemption will be effective January 12, 1986 (unless stayed pending reconsideration). Petitions to stay must be filed by December 23, 1985, and petitions for reconsideration, including environmental, energy, and public use concerns, must be filed by January 2, 1986, with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission should be sent to applicant's representative: Leland E. Butler, 114 Sansome Street, Room 1208, San Francisco, CA 94104.

If the notice of exemption contains false or misleading information, use of the exemption is void *ab initio.*

A notice to the parties will be issued if use of the exemption is conditioned upon environmental or public use conditions.

Decided: December 5, 1985.

By the Commission, Heber P. Hardy, Director, Office of Proceedings.

James H. Bayne,

Secretary.

[FR Doc. 85-29544 Filed 12-12-85; 8:45 am]

BILLING CODE 7035-01-M