

Technical Electronic Product Radiation Safety Standards Committee

The function of the Technical Electronic Product Radiation Safety Standards Committee is to provide advice and consultation on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products. The committee may recommend electronic product radiation safety standards for consideration.

Qualifications

Medical Devices Panels

Persons nominated for membership on the medical devices panels shall have adequately diversified experience appropriate to the work of the panel in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The particular needs at this time for each panel are shown above. The term of office is between 3 and 4 years, depending on the appointment date.

Medical Radiation Advisory Committee

The members of the Medical Radiation Advisory Committee are selected from among authorities in the fields of medicine, dentistry, public health, physics, engineering, and related health sciences who are knowledgeable about the theory, application, and use of radiation in the healing arts. The particular needs at this time for this committee are shown above. The term of office is between 3 and 4 years, depending on the appointment date.

Technical Electronic Product Radiation Safety Standards Committee

Persons nominated for the Technical Electronic Product Radiation Safety Standards Committee must be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety. The particular needs for this committee are shown above. The term of office is between 3 and 4 years, depending on the appointment date.

Nomination Procedure

Any interested person may nominate one or more qualified persons for membership on one or more of the

advisory committees or panels. Self-nominations are also accepted. Nominations shall include a complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

Nominations for the Technical Electronic Product Radiation Safety Standards Committee are being requested now; however, appointments will not occur until there is a need for a meeting.

This notice is issued under the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 [5 U.S.C. App. I]) and 21 CFR Part 14, relating to advisory committees.

Dated: December 8, 1985.

Mervin H. Shumate,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 85-29519 Filed 12-12-85; 8:45 am]

BILLING CODE 4160-01-M

Request for Nominations for Representatives of Consumer and Industry Interests on Public Advisory Committees For Panels

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: Food and Drug Administration (FDA) is requesting nominations for consumer and industry representatives to serve on certain public advisory committees or panels in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and for those that will or may occur during the next 16 months.

FDA has a special interest in ensuring that women, minority groups, the physically handicapped, and small businesses are adequately represented on advisory committees and, therefore, extends particular encouragement to nonnominations for appropriately qualified female, minority, and physically handicapped candidates, and nominations from small businesses that manufacture medical devices subject to the regulations.

DATE: Nominations should be received by January 27, 1986, for vacancies listed in this notice.

ADDRESSES: All nominations and curricula vitae for consumer representatives must be submitted in writing to Naomi Kulakow (address below).

All nominations and curricula vitae (which includes nominee's office address and telephone number) for industry representatives must be submitted in writing to Kay Levin (address below).

FOR FURTHER INFORMATION CONTACT:

For Consumer Interests: Naomi Kulakow, Office of Consumer Affairs (HFE-40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5006.

For Industry Interests: Kay Levin, Center for Devices and Radiological Health (HFZ-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3516.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for members representing consumer and industry interests for the following panels and committee:

Committee or panel	Approximate date representative is needed	
	Consumer	Industry
1. Circulatory System Devices Panel	June 30, 1986	NV ¹
2. Dental Devices Panel	Oct. 31, 1986	NV
3. Device Good Manufacturing Practice Advisory Committee	NV	(2) May 31, 1986
4. Ear, Nose, & Throat Devices Panel	Oct. 31, 1986	NV
5. General Hospital and Personal Use Devices Panel	Dec. 31, 1986	NV
6. Hematology and Pathology Devices Panel	Feb. 28, 1987	NV
7. Immunology Devices Panel	Feb. 28, 1987	NV
8. Neurological Devices Panel	Nov. 30, 1986	NV
9. Obstetrics-Gynecology Devices Panel	NV	Jan. 31, 1987
10. Radiologic Devices Panel	Jan. 31, 1987	NV

¹ NV = No vacancy.

Functions

Medical Devices Panels

The functions of the medical devices panels are to (1) review and evaluate available data concerning the safety and effectiveness of devices currently in use, (2) advise the Commissioner of Food and Drugs regarding recommended classification of these devices into one of three regulatory categories, (3) recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval

category, (4) advise on any possible risks to health associated with the use of devices, (5) advise on formulation of product development protocols and review premarket approval applications for those devices classified in the premarket approval category, (6) review classification of devices to recommend changes in classification as appropriate, (7) recommend exemption to certain devices from the application of portions of the act, (8) advise on the necessity to ban a device, (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

Device Good Manufacturing Practice Advisory Committee

The function of the Device Good Manufacturing Practice Advisory Committee is to review regulations for promulgation regarding good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and make recommendations regarding the feasibility and reasonableness of those proposed regulations. The committee also reviews and makes recommendations on proposed guidelines (e.g., Guideline on General Principles of Process Validation) developed to assist the medical device industry in meeting the good manufacturing practice requirements, and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations.

Consumer and Industry Representation

Section 513 of the act (21 U.S.C. 360c) provides that each medical devices panel include as members one nonvoting representative of consumer interests and one nonvoting representative of interests of the device manufacturing industry. Section 520 of the act (21 U.S.C. 360j) provides that the Device Good Manufacturing Practice Advisory Committee include members two voting representatives of the general public and two voting representatives of interests of the device manufacturing industry.

Nomination Procedure

Any interested person may nominate one or more qualified persons as a member of a particular advisory committee or panel to represent consumer interests as identified in this notice. Self-nominations are also accepted. To be eligible for selection, applicants' experience and/or education

will be evaluated against Federal civil service criteria for the position to which they will be appointed.

Any organization in the medical device manufacturing industry ("industry interests") wishing to participate in the selection of an appropriate member of a particular committee or panel may nominate one or more qualified persons to represent industry interests. Persons who nominate themselves as industrial representatives will not participate in the selection process. It is, therefore, recommended that all nominations made by someone with an organization or firm who is willing to participate in the selection process. Nominations shall include a complete curriculum vitae of each nominee and shall state that the nominee is aware of the nomination, is willing to serve as a member, and, in the case of consumer representative, appears to have no conflict of interest. The nomination should state whether the nominee is interested only in a particular advisory committee or panel or in any advisory committee or panel. The term of office is between 3 and 4 years, depending on the appointment date.

Selection Procedure

Selection of members representing consumer interests is conducted through a procedure which includes use of a consortium of consumer organizations which has the responsibility for screening, interviewing, and recommending candidates to the agency for the agency's selection. Candidates should possess appropriate qualifications to understand and contribute to the committee's work.

Regarding nominations for members representing the interests of the device manufacturing industry, a letter will be sent to each organization that has made a nomination, and to those organizations indicating an interest in participating in the selection process, together with a complete list of all such organizations and the nominee. This letter will state that it is the responsibility of each organization to consult with the others in selecting a single member representing industry interests for that particular committee within 60 days after receipt of the letter.

This notice is issued under the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)) and 21 CFR Part 14, relating to advisory committee.

Dated: December 5, 1985.

Mervin H. Shumate,
Acting Associate Commissioner for
Regulatory Affairs.
[FR Doc. 85-29520 Filed 12-12-85; 8:45 am]
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[Docket No. 80N-0276; DESI 7630]

Drugs for Human Use; Certain Anabolic Steroids; Withdrawal of Approval

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of the new drug applications for methandrostenolone marketed by Bolar Pharmaceutical Co., Inc. The drug lacks substantial evidence of effectiveness. Methandrostenolone, an anabolic steroid, is offered as adjunctive therapy in senile and Postmenopausal osteoporosis.

EFFECTIVE DATE: January 13, 1986.

FOR FURTHER INFORMATION CONTACT: Judy L. O'Neal, 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 January 18, 1983 (48 FR 2206), the Director of the Center for Drugs and Biologics revoked the temporary exemption for certain anabolic steroids. The exemption had permitted the continued marketing of the products beyond the time limit scheduled for implementation of the Drug Efficacy Study. The notice also reclassified the products to lacking substantial evidence of effectiveness in the treatment of osteoporosis and offered an opportunity for a hearing on a proposal to withdraw approval of the new drug applications.

Hearing requests were submitted by Bolar Pharmaceutical Co., Inc., and Par Pharmaceutical, Inc., manufacturers of methandrostenolone. The manufacturers of the other products named in the January 1983 notice did not request a hearing, and approval of those products (and identical, related, and similar products) was withdrawn by the Center in a notice published in the *Federal Register* of May 13, 1983 (48 FR 21658).

On October 21, 1985, the Commissioner of Food and Drugs denied the hearing request of Par and withdrew approval of Par's products (50 FR 42599).

The products named in the January 1983 notice for which Bolar requested a hearing are the following:

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.

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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