devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, notably deliberative sessions to formulate advice and recommendations to the agency on matters that do not independently justify closing.

Dated: January 11, 1983.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 83-1141 Filed 1-17-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82D-0359]

Bioequivalence Studies for New Animal Drugs; Availability of Drug Guideline

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guideline prepared by its Bureau of Veterinary Medicine entitled "Bioequivalence Study Guideline." The guideline is intended for use in establishing the safety and effectiveness of certain new animal drugs through the use of bioequivalency studies. Although FDA advises that the agency will accept bioequivalence studies conducted as described in this draft guideline, it is being made available for public comment to provide FDA with views that will be considered in FDA's development of the final guideline.

ADDRESS: Written comments on the draft guideline and requests for single copies are to be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

DATE: Comments on or before May 18, 1983.

FOR FURTHER INFORMATION CONTACT: Richard P. Lehmann, Bureau of Veterinary Medicine (HFV-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3134.

SUPPLEMENTARY INFORMATION: The Federal Food, Drug, and Cosmetic Act (the act) requires that a new animal drug be the subject of an approved new animal drug application (NADA) before it may be marketed. Section 512(b)(1) of the act (21 U.S.C. 360b(b)(1)) requires that each NADA include full reports of investigations which show that the drug is safe and effective for use. Section 512(d) of the act and § 514.111 (21 CFR 514.111) describe the criteria that an applicant for an NADA must meet to show that a new animal drug is safe and effective and therefore may be approved. In certain instances, the agency has determined that NADA's and supplements to NADA's need not include safety or efficacy data as specified in § 514.111, but may be approved on the basis of bioquivalency studies.

The Bureau of Veterinary Medicine (the bureau) has prepared a draft guideline entitled "Bioequivalence Study Guideline" that may be used where bioequivalency data are acceptable to the bureau, in lieu of safety or efficacy data, for new animal drug approval. The draft guideline is appropriate for use by sponsors seeking approval for either (1) a new animal drug product that is eligible for generic equivalence (at the present time, those that were reviewed by the National Academy of Sciences/National Research Council and deemed effective) that contains an active ingredient(s) in the same dosage form (pharmaceutical equivalent) as an approved new animal drug product of another sponsor; (2) a change in the manufacturing process, including a change in product formulation or dosage strength, for a product for which the sponsor holds an approved NADA; or (3) a different dosage form (pharmaceutical alternative) from that for which clinical data are available.

A significant aspect of this draft guideline is the provision that withdrawal periods for generic new animal drug products for which approval is sought for food animal use may in many cases be established by evaluating the serum level curves generated from a properly conducted study. Until now, companies wishing to market generic equivalent new animal drug products for food animal use have been required to conduct a tissue residue study in addition to the bioequivalency evaluation to determine the appropriate preslaughter withdrawal time. The change of bureau policy proposed in this draft guideline should result in savings of research animals and funds used in the development of certain new animal drug products, thereby providing regulatory relief to the affected industry while assuring the safety and effectiveness of the affected new animal drugs. The bureau is making this proposed change based on advances in knowledge in the field of pharmacokinetics and related disciplines, particularly the knowledge that if a generic new animal drug product is proven to be bioequivalent to an approved reference standard product (usually the pioneer approved product) then tissue residue levels will in many instances be identical and, therefore, the generic new animal drug product and the approved reference standard product should have the same withdrawal periods.

This notice of availability is issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidelines to establish procedures of general applicability that are not legal requirements but are acceptable to the agency. A person who follows a guideline is assured that the procedures used for the study will be acceptable to the agency. A person may also choose to use alternative procedures even though they are not provided for in the guideline. A person who chooses to depart from the guideline should discuss the matter further with the agency to prevent expenditure of resources for work that the agency may later determine to be unacceptable.

FDA advises that bioequivalence studies conducted as described in this draft guideline will be accepted by the agency effective immediately. However, FDA is inviting comments from the regulated industry, academia, and other interested persons on the draft guideline. These comments will be considered in determining whether revision of the draft guideline is warranted. FDA will publish in the **Federal Register** a notice of availability of any final guideline adopted in response to this notice. The agency is also prepared to meet with interested parties during the comment period to discuss the draft guideline.

A copy of the draft guideline is on file with the Dockets Management Branch (address above) and interested persons may receive a single copy of the guideline by submitting a request to that office.

Interested persons may, on or before May 18, 1983, submit written comments on the draft guideline to the Dockets Management Branch. Two copies of any comments should be submitted, except that individuals may submit one copy. Submissions should be identified with the docket number found in brackets in the heading of this document. Received comments will be incorporated into the public file on the guideline and may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 6, 1983.

Mark Novitch,

Deputy Commissioner of Food and Drugs.

[FR Doc. 83-1142 Filed 1-17-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 80N-0276; DESI 7630]

Certain Anabolic Steroids; Drug Efficacy Study Implementation; Revocation of Exemption; Opportunity for Hearing

AGENCY: Food and Drug Administration (FDA).

ACTION: Notice.

SUMMARY: This notice revokes the temporary exemption for the continued marketing of certain anabolic steroid drug products. Under the exemption, these products have been allowed to remain on the market for continued study beyond the time limit scheduled for implementing the Drug Efficacy Study. This notice also reclassifies these products to lacking substantial evidence of effectiveness in the treatment of postmenopausal osteoporosis, proposes to withdraw approval of the new drug applications covering these products, and offers an opportunity for a hearing on the proposal. The manufacturers of these products have not complied with previously announced conditions for continued marketing and, in some cases, have informed FDA that they are no longer interested in marketing these products.

DATES: The exemption revocation is effective January 18, 1983, hearing requests are due February 17, 1983. Data supporting hearing request are due March 21, 1983.

ADDRESSES: Communications in response to this notice should be identified with Docket No. 80N-0276 and DESI 7630, and directed to the attention of the appropriate office named below.

Requests for a hearing, supporting data, and comments: Dockets Management Branch (HFA-305), Rm. 4-62, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Requests for opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFN-310), National Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nicholas Reuter, National Center for Drugs and Biologics (HFN-8), 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 24, 1970 (35 FR 10327), FDA announced its conclusions on the effectiveness of certain anabolic steroids, based on reports received from the National Academy of Sciences-National Research Council. The drugs were classified as probably effective for adjunctive therapy in the treatment of senile and postmenopausal osteoporosis. They were also classified as probably effective for pituitary dwarfism because growth hormone was not readily available at that time. The products were classified as either possibly effective or lacking substantial evidence of effectiveness for their other labeled indications.

In a notice published in the Federal Register of December 14, 1972 (37 FR 26623), anabolic steroids were temporarily exempted from the time limits established for the Drug Efficacy Study Implementation (DESI) program pending completion of studies to determine effectiveness. The exemption was granted because there were no products classified as effective for the treatment of postmenopausal osteoporosis. The pituitary dwarfism indication was permitted to remain until growth hormone became more widely available.

Because of the lack of general agreement on parameters to be measured and the techniques for measurement, FDA developed guidelines for the clinical study of drugs used to treat osteoporosis. The availability of the guidelines was announced in the Federal Register of June 20, 1980 (45 FR 41705). Subsequently, FDA announced conditions for continued marketing of anabolic steroids, for the treatment of osteoporosis, while protocols were designed and studies were conducted (45 FR 72292, October 31, 1980). Manufacturers of products that were the subject of "deemed approved" new drug applications (NDA's) were to revise their labeling as required and submit protocols or notify the agency that they would rely on studies conducted by another manufacturer. Abbreviated new drug applications (ANDA's) were required for those products not provided for by an NDA. If one drug sponsor was conducting studies on a product, that was considered sufficient to permit marketing of all firms' products containing the same chemical entity in a similar dosage form provided each product met the other marketing conditions.

Additionally, because growth hormone had become readily available, the marketing conditions required that the indication for pituitary dwarfism be removed from the labeling of anabolic steroids.

Some manufacturers have submitted supplements or ANDA's under the conditions for continued marketing set forth in the October 31, 1980 Federal Register notice. Other manufacturers have not done so, and some have discontinued marketing their products.

I. Revocation of Exemption

This notice revokes the temporary exemption announced in the Federal Register of December 14, 1972, for those drug products whose sponsors have not complied with the October 31, 1980 notice. The exemption is therefore revoked for all products that contain methandriol, methandrostenolone, norethandrolone, or oxymetholone, because no person marketing a product containing any of these ingredients have conducted studies or submitted data in support of effectiveness.

II. Products not in Compliance

Because no data have been submitted demonstrating the effectiveness of the following anabolic steroids, for osteoporosis or any other indication, the Director of the National Center for Drugs and Biologics proposes to withdraw approval of the new drug applications listed below:

1. NDA 8-736; Methylandrostenediol Aqueous Suspension containing methandriol 25 or 50 mg/mL; Maurry Bilogical Co., Inc., South Western Ave., Los Angeles, CA 90047.

2. NDA 11-761; Adroyd Tablets containing oxymetholone 2.5, 5, or 10 mg/tablet; Parke-Davis, Division of Warner-Lambert Co., 201 Tabor Rd., Morris Plains, NJ 07950.

3. NDA 12-226; Dianabol Tablets containing Methandrostenolone 2.5 or 5 mg/tablet; Ciba Pharmaceutical Co., Division Ciba-Geigy Corp., 556 Morris Ave., Summit, NJ 07901.

4. NDA 12-733; Anadrol Tablets containing oxymetholone 2.5 mg/tablet; Syntex Laboratories, Inc., 3401 Hillview Ave., Stanford Industrial Park, Palo Alto, CA 94304.

Under the provisions of the October 31, 1980 Federal Register notice, the manufacturers of the following drug products submitted ANDA's and received conditional approval for marketing. However, because no sponsor is conducting clinical studies on any product containing the drug entity, the products are not in compliance with the conditions for marketing and the Director now proposes to withdraw the conditional approval of these ANDAs:

1. ANDA 87-465; Methandrostenolone 2.5 mg tablets; Bolar Pharmaceutical Co. Inc., 130 Lincoln St., Copiage, NY 11726.
2. ANDA 87-466; Methandrostenolone 5 mg tablets, Bolar Pharmaceutical Co. Inc.
3. ANDA 87-945; Methandrostenolone 5 mg tablets; Par Pharmaceutical Inc., 12 Industrial Ave., Upper Saddle River, NJ 07458.
4. ANDA 87-951; Methandrostenolone 2.5 mg Tablets; Par Pharmaceutical Inc.

NDA approval of the following products has been previously withdrawn for failure to file reports as required by section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)). At the time notices withdrawing approval were published, no conclusions concerning the products' effectiveness had been reached.

1. NDA 7-630; Stenediol Injection containing methandriol 25 or 50 mg/mL; Organon, Inc., 375 Mount Pleasant Ave., West Orange, NJ 07052.
2. NDA 10-400; Nilevar Tablet containing norethandrolone 10 mg/tablet; G. D. Searle & Co., P.O. Box 5110, Chicago, IL 60680.
3. NDA 11-019; Nilevar Injection containing norethandrolone in sesame oil, 25 mg/mL; G. D. Searle & Co.
4. NDA 11-683; Nilevar Drops; containing norethandrolone 83 mg/mL; G. D. Searle & Co.

The four products named immediately above are included in this notice because they did not meet the conditions of the exemption notice. This notice offers the applicants an opportunity to request a hearing concerning all issues relating to the legal status of the product.

III. Products still Subject to the Exemption

This proposal does not apply to the following drug products.

1. NDA 11-891; Durabolin Injection containing nandrolone phenproprionate in sesame oil, 25 or 50 mg/mL; Organon, Inc.
2. NDA 12-885; Winstrol Tablets containing stanozolol, 2 mg/tablet; Winthrop Laboratories, Division of Sterling Drug Inc., 90 Park Ave., New York, NY 10016. (Note: NDA 13-268 for Winsteroid Tablets (stanozolol) listed in the June 24, 1970 notice has been assimilated into NDA 12-885 at the request of the holder because both NDA's cover the same product).
3. NDA 13-132; Deca-Durabolin Injection containing nandrolone decanoate 50 mg/mL; Organon, Inc.
4. ANDA 86-385; Nandrolone Decanote 50 mg/mL; Carter Glogau Laboratories, Inc., 5160 West Bethany Home Rd., Glendale, AZ 85301.
5. ANDA 86-386; Nandrolone Phenproprionate containing 25 mg/mL; Carter Glogau Laboratories, Inc.
6. ANDA 86-598; Nandrolone Decanoate 100 mg/mL; Carter Glogau Laboratories, Inc.
7. ANDA 87-488; Nandrolone Phenproprionate 50 mg/mL; Carter Glogau Laboratories, Inc.

IV. Opportunity for Hearing

On the basis of all data and information available to him, the Director of the National Center for Drugs and Biologics is unaware of any adequate and well-controlled clinical investigation, conducted by experts qualified by scientific training and experience, meeting the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335) and 21 CFR 314.111(a)(5) demonstrating the effectiveness of the drugs that are not in compliance with the conditions established for continued marketing (items I and II above).

Therefore, notice is given to the holders of new drug application No's. 8-736, 11-761, 12-226, and 12-733 and of abbreviated new drug application No.'s 87-465, 87-466, 87-945, and 87-951, and to all interested persons, that the Director of the National Center for Drugs and Biologics proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval or conditional approval of the applications and all amendments and supplements thereto on the ground that new information before him with respect to the drug products, evaluated together with the evidence available to him when the applications were approved, shows there is a lack of substantial evidence that the drug products will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

In addition to the holders of the applications specifically named above, this notice of opportunity for hearing applies to all persons (except those in compliance with the terms of the exemption) who manufacture or distribute a drug product, not the subject of an approved application, that is identical, related, or similar to a drug product name above, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice of opportunity for a hearing to determine whether it covers any drug product that the person manufactures or distributes. Such person may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Drug Labeling Compliance (address given above).

In addition to the ground for the proposed withdrawal of approval stated above, this notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in 21 CFR 310.6), e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act or because it is exempt from part or all of the new drug provisions of the act under the exemption for products marketed before June 25, 1938, contained in section 201(p) of the act, or under section 107(c) of the Drug Amendments of 1962, or for any other reason.

In accordance with section 505 of the act (21 U.S.C. 355) and the regulations promulgated under it (21 CFR Parts 310, 314), the applicants and all other persons subject to this notice under 21 CFR 310.6 are hereby given an opportunity for a hearing to show why approval of the applications should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products named above and of all identical, related, or similar drug products.

An applicant or any other person subject to this notice under 21 CFR 310.6 who decides to seek a hearing shall file (1) on or before February 17, 1983, a written notice of appearance and request for hearing, and (2) on or before March 21, 1983, the data, information, and analysis relied on to justify a hearing as specified in 21 CFR 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of appearance and request for hearing, a submission of data, information, and analysis to justify a hearing, other comments, and a grant or denial of hearing are contained in 21 CFR 314.200.

The failure of an applicant or any other person subject to this notice under 21 CFR 310.6 to file a timely written notice of appearance and request for hearing as required by 21 CFR 314.200 constitutes an election by the person not to make use of the opportunity for a hearing concerning the action proposed with respect to the product and constitutes a waiver of any contentions concerning the legal status of any such drug product. Any such drug product may not thereafter lawfully be marketed, and the Food and Drug Administration will initiate appropriate

regulatory action to remove such drug products from the market. Any new drug product marketed without an approved application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that there is not a genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner for Food and Drugs will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice shall be filed in four copies. Such submissions, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052–1053, as amended (21 U.S.C. 355)), and under authority delegated to the Director of the National Center for Drug and Biologics (see 21 CFR 5.82 and 47 FR 26913 published in the **Federal Register** of June 22, 1982).

Dated: January 10, 1983.

Harry M. Meyer, Jr.,

Director, National Center for Drugs and Biologics.

[FR Doc. 83-1144 Filed 1-17-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82F-0390]

Hercules, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Hercules, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of hydrogenated styrene polymer resins as components of adhesives used in articles intended for packaging, transporting, or holding food.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204; 202–472–5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAB 3B3692) has been filed by Hercules, Inc., Wilmington, DE 19899, proposing that Part 175 (21 CFR Part 175) be amended to provide for the safe use of hydrogenated styrene polymer resins as components of adhesives used in articles intended for packaging, transporting, or holding food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: January 6, 1983.

Sanford A. Miller,

Director, Bureau of Foods

[FR Doc. 83-1305 Filed 1-17-83; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Arizona, Safford District Grazing Advisory Board; Meeting

Notice is hereby given in accordance with Pub. L. 92–463 that a meeting of the Safford District Grazing Advisory Board will be held on Friday, February 18, 1983.

The meeting will begin at 9:00 a.m. in the Conference Room of the Bureau of Land Management, 425 E. 4th Street, Safford, Arizona 85546.

The agenda for the meeting will include:

1. Election of Chairman and Vice-chairman;
2. Discussion of Range Improvement policy;
3. Cooperative range improvement development and maintenance;
4. Asset management;
5. BLM management update;
6. Business from the floor.

The meeting will be open to the public. Interested persons may make oral statements to the Board between 10:00 a.m. and 11:00 a.m. A written copy of the oral statement must be provided at the conclusion of the presentation. Written statements may also be filed for the Board's consideration. Anyone wishing to make an oral statement must notify the District Manager, Bureau of Land Management, 425 E. 4th Street, Safford, Arizona 85546, by 4:15 p.m., Thursday, February 17, 1983.

At the conclusion of that session the Board members will depart via BLM-provided vehicles for a field trip to Bonita Creek. Members of the public may accompany the tour but must provide their own transportation. It is expected the Board members will return to the Safford District Office at approximately 4:00 p.m.

Summary Minutes of the Board Meeting will be maintained in the District Office and will be available for public inspection and reproduction (during regular business hours) within thirty (30) days following the meeting.

Dated: January 10, 1983.

Vernon L. Saline,

Acting District Manager.

[FR Doc. 83-1311 Filed 1-17-83; 8:45 am]

BILLING CODE 4310-84-M

Meeting of the California Desert District Advisory Council

Notice is hereby given in accordance with Public Laws 92–463 and 94–579 that the California Desert District Advisory Council to the Bureau of Land Management, U.S. Department of the Interior, will meet formally Friday, February 4 and Saturday, February 5, 1983, in the Pasadena Convention Center, 300 E. Green Street, Room 316, Pasadena, California. The meetings will be from 9 a.m. to 5 p.m. both days.

The two day session will provide a forum for public discussion and a critique of BLM's management of the public lands since adoption of the California Desert Plan in 1980. Interest groups will have the opportunity to raise new issues, evaluate the effect of the Plan with respect to their interests and submit recommendations for change.

The agenda will also include: the appointment of new members to the Council; a brief report on 1982 Plan Amendments; a subcommittee report on the Escondido Project and a report on a state-wide trail system for off-highway vehicles proposed by the State of California, Department of Parks and Recreation.

The meeting is open to the public, with time allotted for comments from the general public. Statements may be filed in advance to Desert Advisory Council Chairman Clayton A. Record, Jr., Public Affairs Office, 1695 Spruce Street, Riverside, California 92507.

For further information and meeting confirmation contact the California