Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: April 20, 1995.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–10197 Filed 4–25–95; 8:45 am]

BILLING CODE 4163–19–P

National Committee on Vital and Health Statistics (NCVHS) Executive Subcommittee: Meeting

Pursuant to Pub. L. 92–463, the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), announces the following committee meeting.

Name: NCVHS Executive Subcommittee.

Time and Date: 8:30 a.m.–5 p.m., May 24, 1995.

Place: Suite 200 East, Conference Room 002–003, 1100 New York Avenue, NW., Washington, DC 20005.

Status: Open.

Purpose: The purpose of this meeting is for the Executive Subcommittee to review accomplishments, logistics, needs and work plans of NCVHS and individual subcommittees.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and a roster of committee members may be obtained from Gail F. Fisher, Ph.D., Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436–7050.

Dated: April 20, 1995.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–10198 Filed 4–25–95; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 95N–0013]

Benton County Ag Center, Inc.; Proposal to Withdraw Approval of Applications for Medicated Animal Feeds; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Veterinary Medicine (CVM), Food and Drug Administration (FDA), is providing an opportunity for a hearing on a proposal to withdraw approval of certain medicated feed applications (MFA's) held by Benton County Ag Center, Inc., for animal feeds bearing or containing new animal drugs (NAD's). This action is based on new information showing the firm's methods and controls used for manufacturing, processing, and packing of the medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the NAD's therein, and they were not made adequate within a reasonable time after receipt of written notice from FDA.

DATES: Requests for a hearing and data and information in support of the hearing request are due by May 26, 1995.

ADDRESSES: Requests for a hearing in response to this notice should be identified with Docket No. 95N–0013 and sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Karen A. Kandra, Center for Veterinary Medicine (HFV–246), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1765.

SUPPLEMENTARY INFORMATION: CVM is providing an opportunity for a hearing on a proposal to withdraw approval of 11 MFA's held by the firm doing business as Benton County Ag Center, Inc., 312 Railroad St., P.O. Box 308, Keystone, IA 52249–0308, for the manufacture of animal feeds bearing or containing Category II NAD's. Benton County Ag Center, Inc., is a feed mill that manufactures both medicated and nonmedicated animal feeds. The 11 MFA's, held by Benton County Ag Center, Inc., were approved under section 512(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(m)) and are identified as follows:

MFA Number	Drug/Combination	Species
1. F 93–642.	Carbadox	Swine
2. F 127–333.	Tylosin/ Sulfamethazine.	Swine
3. F 131–878.	Carbadox	Swine
4. F 139–280.	Levamisole Hydrochloride.	Cattle and swine
5. F 141–603.	Carbadox/ Pyrantel tartrate.	Swine
6. F 141–604.	Pyrantel tartrate	Swine
7. F 141–757.	Lincomycin/ Pyrantel tartrate.	Swine
8. F 144–054.	Sulfamethazine/ Chlortetracycline (CTC)/Penicillin.	Swine
9. F 147–607.	Sulfamethazine/ CTC.	Cattle
10. F 147–617.	Arsanilic acid	Chickens, turkeys, and swine
11. F 147–641.	Oxytetracycline/ Neomycin.	Chickens, turkeys, swine, cattle, and mink

To manufacture a Type B or C animal feed bearing or containing a Category II NAD (i.e., Type A medicated article) a firm must file an MFA (Form FDA 1900) with FDA and obtain its approval. FDA does not approve such an application unless, among other things, the firm agrees to comply with the agency's regulations for current good manufacturing practice (CGMP) for medicated feeds (21 CFR part 225), which are intended to help assure that feed bearing or containing an NAD meets the requirements of the act pertaining to identity, strength, quality, and purity. The agency determines whether the firm's manufacture of medicated feed is in compliance with the CGMP regulations by inspecting the facilities and controls used for, and the methods used in, the manufacture, processing, and packing of the feed by the firm.

On December 22, 1992, the Iowa Department of Agriculture (Medicated Feed Bureau), under contract with FDA pursuant to section 702(a) of the act (21 U.S.C. 372(a)), inspected Benton County Ag Center, Inc. The inspection revealed significant deviations from the CGMP's for medicated feeds. The investigator noted the deviations on an inspectional observations form (Form FDA 483) (Ref. 1), issued a copy to the firm's General Manager, and discussed in detail the deviations with him. The deviations included the following:

1. Production records did not show when flushing of equipment was performed or the final disposition of flush materials, as required by 21 CFR 225.102(b)(4).

2. Production records did not show the actual quantity of medicated feed produced, as required by 21 CFR 225.102(b)(2)(iv).

3. Production records were not checked by a responsible person to determine if all required production steps had been performed, as required by 21 CFR 225.102(b)(4).

4. Only two of the three required assays were performed on medicated feeds containing monensin and melengestrol acetate, as required by 21 CFR 225.58(b)(1).

5. Proper labeling for medicated feed manufactured containing 300 grams per ton chlortetracycline was not available, as required by 21 CFR 225.80.

6. The drug scale, ingredient scale, and the bagger scale had not been tested for accuracy within the last year, as required by 21 CFR 225.30(b)(4).

7. No written procedures for flushing and sequencing were available, as required by 21 CFR 225.65(b).

8. Incoming labels were not proofread, dated, or initialed by a responsible person, as required by 21 CFR 225.80(b)(2).

9. No investigation or corrective action was taken after receipt of failed assay result for medicated feed, as required by 21 CFR 225.58(d) and (e).

10. No drug receipt records or daily drug inventory were maintained for Category I, Type A medicated articles, as required by 21 CFR 225.42(b)(5) and (b)(6).

As a result of the failed CGMP inspection, FDA sent a letter dated March 12, 1993 (Ref. 2), (with a copy of the Form FDA 483 enclosed) to the firm's president. The letter discussed potential regulatory consequences that could result due to facility personnel deviating from CGMP requirements. It urged that the firm's president ''* * * ensure complete and **lasting** [emphasis added] correction of all regulatory deficiencies.'' The letter also informed the firm's president that FDA would not approve additional MFA's until the violations were corrected and verified. Finally, the letter closed by stating that if the violations were not corrected, FDA might issue a notice of opportunity for a hearing on a proposal to withdraw approval of the firm's MFA's.

In response to the FDA letter, the firm's president sent a letter dated April 7, 1993 (Ref. 3), to FDA listing the actions that had been taken to correct all violations listed on the Form FDA 483.

The firm was inspected again on May 3, 4, 10, and 11, 1994. That inspection revealed continued violations of CGMP regulations for the manufacture of medicated animal feeds including the following:

1. Failed assay results had not been investigated, and the required corrective actions had not been instituted, as required by 21 CFR 225.58(d) and (e).

2. The three drug potency assays required per calendar year were not performed on medicated feeds containing Aureo S 700 (chlortetracycline and sulfamethazine), as required by 21 CFR 225.58(b)(1).

3. Master Record Files did not always indicate the amount of drug source material to be used in a batch of medicated feed, as required by 21 CFR 225.102(b)(1).

4. Liquid meters to measure molasses and white grease had not been tested for accuracy within the last year, as required by 21 CFR 225.30(b)(4).

5. A container (bearing expiration date 10/92) with 10 pounds of tiamulin indicated inadequate drug control, as required by 21 CFR 225.42(a).

A Form FDA 483 (Ref. 4) containing the observed violations was presented to and discussed with the firm's president.

Consequently, FDA sent a certified letter dated August 23, 1994 (Ref. 5), to the president of Benton County Ag Center, Inc., notifying him of FDA's intention to withdraw approval of the 11 MFA's currently held by his firm. The firm has not submitted a formal response to the letter.

Accordingly, FDA is now proposing to withdraw approval of the MFA's held by Benton County Ag Center, Inc., as identified above, under section 512(m)(4)(B)(ii) of the act and 21 CFR 514.115(c)(2).

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Form FDA 483, inspection of December 22, 1992.

2. Letter, FDA to Benton County Ag Center, Inc., dated March 12, 1993.

3. Letter, Benton County Ag Center, Inc., to FDA, dated April 7, 1993.

4. Form FDA 483, inspection of May 3, 4, 10, and 11, 1994.

5. Letter, FDA to Benton County Ag Center, Inc., dated August 23, 1994.

Therefore, notice is given to Benton County Ag Center, Inc., and to any other interested persons who may be adversely affected, that CVM proposes to issue an order under section 512(m)(4)(B)(ii) of the act and 21 CFR 514.115(c)(2) withdrawing approval of MFA's F 93–642, F 127–333, F 131–878, F 139–280, F 141–603, F 141–604, F 141–757, F 144–054, F 147–607, F 147–617, F 147–641, and all amendments and supplements thereto, on the grounds that new information, evaluated together with the evidence available when the applications were approved, shows that the methods used in, or the facilities and controls used for, the manufacturing, processing, and packing of such animal feeds are: (1) Inadequate to ensure and preserve the identity, strength, quality, and purity of the NAD's therein, and (2) were not made adequate within a reasonable time after receipt of written notice from FDA specifying the inadequacies.

In accordance with provisions of section 512 of the act and regulations promulgated for the efficient enforcement of it (21 CFR part 514), and under authority delegated to the Director, Center for Veterinary Medicine (21 CFR 5.84), CVM hereby provides an opportunity for a hearing to show why approval of the MFA's identified in this notice, and all amendments and supplements to the applications, should not be withdrawn under section 512(m)(4)(B)(ii) of the act and 21 CFR 514.115(c)(2). Any hearing would be subject to the provisions of 21 CFR part 12.

An applicant who decides to seek a hearing shall file on or before May 26, 1995, a written notice of appearance, request for a hearing, and the data, information, and analyses relied on to justify a hearing, as specified in 21 CFR 514.200.

Procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance and request for a hearing, submission of information and analysis to justify a hearing, other comments, and a grant or denial of a hearing, are contained in 21 CFR 514.200.

The failure of a sponsor to file a timely, written appearance and request for a hearing as required by 21 CFR 514.200 shall be construed as an election not to avail himself of the opportunity for a hearing. In such case, the Director, Center for Veterinary Medicine, under the authority delegated to him in 21 CFR 5.84(a)(2), without further notice will enter a final order withdrawing approval of the applications.

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 clearly appears from the face of the documentation and analysis in the request for a hearing that there is no

genuine and substantial issue of fact that precludes the withdrawal of approval of the MFA's, or that the request for a hearing is not made in the required format or with the required analysis, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing. If a hearing is requested and is justified by the sponsor's response to this notice, the issues will be defined, an administrative law judge will be assigned, and a written notice of the time and place at which the hearing will begin will be issued as soon as practicable.

All submissions under this notice shall be filed in four copies and, except as provided in 21 CFR 10.20(j), may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 512 (21 U.S.C. 360b)) and under authority delegated to the Director, Center For Veterinary Medicine (21 CFR 5.84).

Dated: April 19, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–10274 Filed 4–25–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0101]

Warren Teed Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 107 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 107 abbreviated new drug applications (ANDA's). The holders of the ANDA's notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: May 26, 1995.

FOR FURTHER INFORMATION CONTACT: Carolyn C. Harris, Center for Drug Evaluation and Research (HFD–360), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1038.

SUPPLEMENTARY INFORMATION: The holders of the ANDA's 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
83–076	Sulfasalazine, 500 milligrams (mg)	Warren Teed Pharmaceuticals, Inc., Columbus, OH 43215.
83–078	Chlorpheniramine Maleate Tablets, 4 mg	Anabolic, Inc., P.O. Box C–19508, Irvine, CA 92713.
83–135	Lidocaine Hydrochloride Injection, U.S.P., 1% and 2%	G. D. Searle and Co., P.O. Box 5110, Chicago, IL 60680.
83–168	Hydrocortisone Liquid, 1% and 2 1/2%	Dermik Laboratories, Inc., 500 Arcola Rd., P.O. Box 1200, Collegeville, PA 19426–0107.
83–169	Hydrocortisone Gel, 1% and 2 1/2%	Do.
83–184	Propoxyphene Hydrochloride Capsules, 65 mg	Smith, Kline & French, One Franklin Plaza, P.O. Box 7929, Philadelphia, PA 19101.
83–275	Diphenhydramine Hydrochloride Capsules, U.S.P., 50 mg	Anabolic, Inc.
83–301	Pentobarbital Sodium Capsules, 100 mg	Purepac Pharmaceutical, Co., 200 Elmora Ave., Elizabeth, NJ 07207.
83–313	Triamcinolone Acetonide Ointments, 0.025%, 0.1%, and 0.5%.	Dermik Laboratories, Inc.
83–314	Triamcinolone Acetonide Creams, 0.025%, 0.1%, and 0.5%.	Do.
83–363	Metaraminol Bitartrate Injection, U.S.P., 10 mg/milliliters (mL).	Elkins-Sinn, Inc., Two Esterbrook Lane, Cherry Hill, NJ 08003–4099.
83–554	Hydrochlorothiazide Tablets, 50 mg	Smith, Kline & French.
83–567	Diphenhydramine Hydrochloride Capsules, 50 mg	West-Ward Pharmaceutical Corp., 465 Industrial Way, West, Eatontown, NJ 07724.
83–625	Tripelennamine Hydrochloride Tablets, U.S.P., 25 mg	Warner-Lambert, 201 Tabor Rd., Morris Plains, NJ 07950.
83–626	Tripelennamine Hydrochloride Tablets, U.S.P., 50 mg	Do.
84–125	Dextroamphetamine Sulfate Tablets, 5 mg and 10 mg	Purepac Pharmaceutical, Co.
84–239	Hydrocortisone Tablets, 10 mg	Warner-Lambert.
84–240	Prednisone Tablets, 5 mg	Do.
84–242	Prednisolone Tablets, 5 mg	Do.
84–530	Aminophylline Tablets, 200 mg	The Vale Chemical Co., Inc., Allentown, PA 18102.
84–531	Aminophylline Tablets, 100 mg	Do.
84–601	Chlordiazepoxide Hydrochloride Capsules, 10 mg	Mylan Pharmaceuticals, Inc., P.O. Box 4310, 781 Chestnut Ridge Rd., Morgantown, WV 26505–4310.
84–699	Aminophylline Tablets, 100 mg	Purepac Pharmaceutical, Co.
84–739	Theophylline Elixir, 80 mg/15 mL	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228.
84–880	Hydrochlorothiazide Tablets, 25 mg and 50 mg	Mylan Pharmaceuticals, Inc.
85–112	Hydrochlorothiazide Tablets, 50 mg	Do.
85–195	Meclizine Hydrochloride Tablets, 12.5 mg	Circa Pharmaceuticals, 15 Grand Park Blvd., Athens, OH 45701.
85–375	Acetaminophen Capsules, 500 mg Oxycodone Hydrochloride Capsules, 4.5 mg Oxycodone Terephthalate Capsules, 0.38 mg.	McNeil Pharmaceutical, Welsh and Mckeon Rds., Spring House, PA 19477–0776.
85–534	Sulfisoxazole Tablets, 500 mg	Chelsea Laboratories, Inc., 896 Orlando Ave., West Hempstead, NY 11552.
85–564	Aminophylline Tablets, 200 mg	Do.
85–567	Aminophylline Tablets, 100 mg	Do.