

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

MFA Number	Drug/Combination	Species
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).