EXHIBIT DD

TO DECLARATION OF
JENNIFER A. SORENSON

Penicillin and Tetracycline in Animal Feeds,
48 Fed. Reg. 4554 (Feb. 1, 1983)

ADDRESS: Findlay Street Neighborhood House, Findlay and Baymiller Sts., Cincinnati, OH 45214.

FOR FURTHER INFORMATION CONTACT: Ruth E. Weisheit, Consumer Affairs Officer, Food and Drug Administration, 601 Rockwell Ave., Rm. 463, Cleveland, OH 44114, 216-522-4844.

Cincinnati District Office, chaired by James C. Simmons District Director.

DATE: Wednesday, March 16, 1 p.m.

ADDRESS: Federal Bldg., 200 W. Second St., Rm. 504, Dayton, OH 45402

FOR FURTHER INFORMATION CONTACT: Ruth E. Weisheit, Consumer Affairs Officer, Food and Drug Administration, 601 Rockwell Ave., Rm. 463, Cleveland, OH 44114, 216-522-4844.

Cincinnati District Office, chaired by James C. Simmons, District Director.

DATE: Thursday, March 17, 10 a.m.

ADDRESS: Federal Bldg., 550 Main St., Rm. 5409 Cincinnati, OH 45202.

FOR FURTHER INFORMATION CONTACT: Ruth E. Weisheit, Consumer Affairs Officer, Food and Drug Administration, 601 Rockwell Ave., Rm. 463, Cleveland, OH 44114, 216-522-4844.

SUPPLEMENTARY INFORMATION: The purpose of these meetings is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's District Offices, and to contribute to the agency's policymaking decisions on vital issues.

Dated: January 25, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-2643 Filed 1-31-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket Nos. 75N-0223, 75N-0184; DESI 3265, 9489]

Drugs for Human Use; Drug Efficacy Study Implementation; Certain Anticholinergic Drugs Containing Tridihexethyl Chloride; Withdrawal of Approval

AGENCY: Food and Drug Administration (FDA).

ACTION: Notice.

SUMMARY: This notice withdraws approval of the new drug application (NDA 11-889) for Pathilon Sequels and those parts of the new drug application (NDA 9-489) pertaining to Pathilon with Phenobarbital Tablets. The basis of the withdrawal is that there is a lack of substantial evidence that these drugs are effective in the treatment of various gastrointestional disorders. The drug products are no longer marketed.

EFFECTIVE DATE: March 3, 1983.

ADDRESS: Requests for an opinion of the applicability of this notice to a specific product should be identified with the reference numbers DESI 3265 or DESI 9489 (whichever is applicable) and directed to the Division of Drug Labeling Compliance (HFN-310), National Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20850.

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 notices published in the Federal Register of November 11, 1975 (40 FR 52651), and January 16, 1981 (46 FR 3977), the Director of the Bureau of Drugs proposed to withdraw approval of the new drug applications for certain anticholinergic drugs used for the treatment of various gastrointestinal disorders. The notices addressed both anticholinergic/sedative combinations and single-entity anticholinergics; however, the November 11, 1975 notice specified controlled-release formulations, while the January 16, 1981 notice referred to conventional dosage forms. Each notice offered an opportunity for a hearing on the proposal. The proposals were based on the lack of substantial evidence of effectivness as required by section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), 21 CFR 314.111(a)(5), and, for combination products, 21 CFR 300.50.

Lederle Laboratories requested a hearing for Pathilon Sequels (NDA 11-889) in response to the 1975 notice and for Pathilon with Phenobarbital Tablets (NDA 9-489) in response to the 1981 notice. Subsequently, on December 30, 1982, Lederle withdrew its hearing requests as they pertained to these products.

Accordingly, the Director of the National Center for Drugs and Biologics withdraws approval of the new drug applications (or appropriate parts thereof) listed below.

1. NDA 9-489; those parts that provide for Pathilon with Phenobarbital Tablets containing tridihexethyl chloride (25 mg) and phenobarbital (15 mg); Lederle Laboratories, Division of American Cyanamid Co., One Cyanamid Plaza, Wayne, NJ 07470.

This notice does not apply to Pathilon Tablets (NDA 9-489) containing single-entity tridihexethyl chloride, which is classified as effective for the adjunctive treatment of peptic ulcer. Pathilon Tablets is also the subject of a pending hearing request for certain less-than-effective indications whose efficacy evaluation has not been finalized.

2. NDA 11-889; Pathilon Sequels containing tridihexethyl chloride (75 mg) in controlled release forms; Lederle Laboratories.

Any drug product that is identical, related, or similar to these products and is not the subject of an approved new drug application is covered by the new drug applications reviewed and is subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Drug Labeling Compliance (address given above).

The Director of the National Center for Drugs and Biologics, under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1051-1053, as amended (21 U.S.C. 355)), and under the authority delegated to him (21 CFR 5.82 and 47 FR 26913 published in the Federal Register of June 22, 1982), 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 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 their labeling.

Therefore, pursuant to the foregoing finding, approval of those parts of NDA 9-489 that provide for the drug product named above, and approval of NDA 11-889, and all amendments and supplements thereto, are withdrawn effective March 3, 1983.

Shipment in interstate commerce of the above products, or any identical, related, or similar product that is not the subject of an approved new drug application, will then be unlawful.

Dated: January 25, 1983.

Harry M. Meyer, Jr.,

Director, National Center for Drugs and Biologics.

[FR Doc. 83-2645 Filed 1-31-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket Nos. 77N-0230, 77N-0231, 77N-0316, 77N-0317, and 77N-0318]

Penicillin and Tetracycline (Chlortetracycline and Oxytetracycline) in Animal Feeds; Denial of Petitions

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is denying petitions for withdrawal of its notices of opportunity for hearing on its proposed withdrawal of approval of certain uses of penicillin and tetracycline (chlortetracycline and oxytetracycline) in animal feeds; its advanced notice of hearing on the proposed withdrawals; and its proposal to restrict medicated feeds containing such drugs to use by or in the order of a licensed veterinarian.

FOR FURTHER INFORMATION CONTACT: Philip J. Frappaolo, Bureau of Veterinary Medicine (HFV-232), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md 20857, 301-443-4940.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 30, 1977 (42 FR 43772), the Director of the Bureau of Veterinary Medicine (the Director) issued a notice of opportunity for hearing proposing to withdraw approval of new animal drug applications (NADA's) for all penicillin-containing premixes intended for use in animal feeds on the grounds that evidence showed that such products have not been shown to be safe; that the applicants failed to establish and maintain records and make reports as required; and that new evidence has shown that there is a lack of substantial evidence that such products are effective for certain uses. The Director issued a similar notice of opportunity for hearing concerning certain subtherapeutic uses of tetracyclines (chlortetracycline and oxytetracycline) in animal feeds in the **Federal Register** of October 21, 1977 (42 FR 56264). The Director issued the notices after evaluating data submitted by the sponsors of the NADA's in response to requirements imposed by § 558.15 *Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals* (21 CFR 558.15).

The Commissioner of Food and Drugs (the Commissioner) subsequently published an advance notice of public hearing on the proposed withdrawal of approvals (43 FR 53827; November 17, 1978). However, the Commissioner did not issue a formal notice of hearing as provided by 21 CFR Part 12.

The Commissioner also published a proposal to restrict the use of penicillin, chlortetracycline, and oxytetracycline in animal feeds to use by or on the order of a licensed veterinarian (43 FR 3032; January 20, 1978). On August 8, 1978 (43 FR 35059), the Commisioner issued a notice postponing final action on that proposal.

Thereafter, Congress directed FDA to contract with the National Academy of Sciences (NAS) to study issues related to the use of antibiotics in animal feeds. Congressional committee report language also stated that FDA should hold in abeyance implementation of its proposed withdrawal actions pending final results of this study.

The NAS committee concluded that it is technically not possible to conduct a single comprehensive epidemiological study which would settle the issues, but suggested several studies that could provide useful information. In view of the NAS report, Congreess instructed FDA to conduct the additional studies to collect epidemiological information consistent with the NAS suggestions. These studies will not be completed before 1984. Congress has continued to state that FDA will, in the meantime, be expected to hold in abeyance any implementation of its proposals to restrict subtherapeutic uses of penicillin, chlortetracycline, and oxytetracycline in animal feeds.

In July 1981, sponsors of the NADA's that are the subject of the notices of opportunity for hearing petitioned the agency to vacate the notices of opportunity for hearing, the advance notice of hearing, and the notice of proposed rulemaking. The sponsors also asked the agency to permit approval of new uses and combinations of previously approved products. The petitions received are as follows:

Citizen petition	Petitioner	Docket No.	Date received
Penicillin-containing premixes	American Cyanamid Co	77N-0230/CP	July 8, 1981.
Penicillin in animal feeds	American Cyanamid Co	77N-/0231/CP	Do.
Penicillin/tetracycline-containing premixes	American Cyanamid Co	77N-0316/CP	Do.
Proposal to revise tetracycline regulations	American Cyanamid Co	77-0317/CP	Do.
Animal feeds containing penicillin and tetracycline.	American Cyanamid Co	77-0318/CP	Do.
Penicillin-containing premixes	Daimond Shamrock Co.	77-0230/CP0002	July 9, 1981.
Penicillin-containing premixes	Rachelle Laboratories, Inc	77N-0230/CP0003	Do.
Penicillin in animal feeds	Diamond Shamrock Corp	77N-0231/CP0002	Do.
Penicillin in animal feeds	Rachelle Laboratories, Inc	77N-0231/CP0003	Do.
Penicillin/tetracycline-containing premixes	Diamond Shamrock Corp	77N-0316/CP0002	Do.
Penicillin/tetracycline-containing premixes	Rachelle Laboratories, Inc	77N-0318/CP0003	Do.
Proposal to revise tetracycline regulations	Diamond Shamrock Corp	77N-0317/CP0002	Do.
Proposal to revise tetracycline regulations	Rachelle Laboratories, Inc	77N-0317/CP0003	Do.
Animal feeds containing penicillin and tetracycline.	Diamond Shamrock Corp	77N-0318/CP0002	Do.
Animal feeds containing penicillin and tetracycline.	Rachelle Laboratories, Inc	77N-0318/CP0003	Do.
Penicillin-containing premixes	Pfizer, Inc	77N-0230/CP0004	July 15, 1981.
Penicillin in animal feeds	Pfizer, Inc	77N-0231/CP0004	Do.
Penicillin/tetracycline-containing premixes	Pfizer, Inc	77N-0316/CP0004	Do.
Proposal to revise tetracycline regulations	Pfizer, Inc	77N-0317/CP0004	Do.
Animal feeds containing penicillin and tetracycline.	Pfizer, Inc	77N-0318/CP0004	Do.
Penicillin-containing premixes	Merck & Co., Inc	77N-0230/CP0005	July 2, 1981.
Penicillin in animal feeds	Merck & Co., Inc	77N-0231/CP0005	Do.
Penicillin/tetracycline-containing premixes	Merck & Co., Inc	77N-0316/CP0005	Do.
Proposal to revise tetracycline regulations	Merck & Co., Inc	77N-0317/CP0005	Do.
Animal feeds containing penicillin and tetracycline.	Merck & Co., Inc	77N-0318/CP0005	Do.

The Commissioner has concluded that approval of new applications and supplements for penicillin, chlortetracycline, and oxytetracycline should be permitted, but that § 558.15 must first be amended. Accordingly, the proposal to amend § 558.15 is published elsewhere is this issue of the **Federal Register.**

With respect to the pending notices of opportunity for hearing, the petitioners argued that any future agency action to withdraw approvals will occur only after review of the findings of the studies authorized by Congress. The petitioners' implied position is that if, after agency review of the data, FDA concludes that withdrawal is warranted, it would need to substantially revise the notices. Therefore, the agency should withdraw its notices of opportunity for hearing at this time.

However, the Director[1] does not have any less concern at present about the safety issues that prompted adoption of § 558.15 and publication of the notices of opportunity for hearing. The Director has not changed his earlier conclusion that the available scientific information warrants the proposed actions. In fact, recently published research further substantiates this position. See O'Brien,

[1] The current Director, Dr. Lester M. Crawford, is not participating in this proceeding, having been a consultant during 1981 to American Cyanamid Co., one of the sponsors, and the Natural Resources Defense Council, with respect to issues contained in this proceeding. The responsibilities of "the Director" are assumed in this proceeding by Deputy Director Gerald B. Guest.

T. F., et al., "Molecular Epidemiology of Antibiotic Resistance in Salmonella from Animals and Human Beings in the United States," *The New England Journal of Medicine*, July 1, 1982, Vol. 107, No. 1, p. 1.

The notices of opportunity for hearing represent the Director's formal position that use of the drugs is not shown to be safe. Therefore, the Director has concluded that he does not wish to withdraw the notices of opportunity for hearing. Instead, the Director wishes to place the notices in abeyance pending completion of the studies mandated by Congress.

The Commissioner has reviewed the Director's decision and concurs with it. In addition, for the reasons discussed above, the Commissioner has decided that he will not withdraw the advance notice of hearing or the proposal to restrict therapeutic approvals to prescription use, but will hold them in abeyance.

Dated: January 1, 1983.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 83-2644 Filed 1-31-83; 8:45 am]

BILLING CODE 4160-01-M

National Institutes of Health

National Institute of General Medical Sciences; Meetings

Pursuant to Pub. L. 92-463, notice is hereby given of the meetings of the committees of the National Institute of Medical Sciences for March 1983.

These meetings will be open to the public to discuss administrative details relating to committee business for approximately one hour at the beginning of the first session of the first day of the meeting. Attendance by the public will be limited to space available. These meetings will be closed thereafter in accordance with provisions set forth in Section 552b(c)(4) and 552(c)(6), Title 5, U.S. Code and Section 10(d) of Pub. L. 92-463, for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Ann Diffenbach, Public Information Officer, National Institute of General Medical Sciences, National Institutes of Health, Room 9A10, Westwood Building, Bethesda, Maryland 20205 (Telephone: 301-496-7301), will provide a summary of the meeting and a roster of committee members.

Substantive program information may be obtained from each executive secretary whose name, room number, and telephone number are listed below each committee.

Name of committee: Cellular and Molecular Basis of Disease Review Committee
Executive secretary: Dr. Helen Sunshine, Room 950 Westwood Building, Telephone: 301-496-7125
Date of meeting: March 25, 1983
Place of meeting: Linden Hill Hotel, Bethesda, Maryland
Open: March 25, 1983, 8:30 a.m.-9:30 a.m.
Closed: March 25, 1983, 9:30 a.m.-adjournment
Name of committee: Minority Access to Research Careers Review Committee
Executive secretary: Dr. Harriet Gordon, Room 949 Westwood Building, Telephone: 301-496-7585
Dates of meeting: March 7-8, 1983
Place of meeting: Building 31C, Conference Room 6, National Institutes of Health
Open: March 7, 1983, 9:00 a.m.-10:00 a.m.
Closed: March 7, 1983, 10:30 a.m.-5:00 p.m.; March 8, 1983, 9:00 a.m.-adjournment
Name of committee: Pharmacological Sciences Review Committee
Executive secretary: Dr. Anthony Demsey, Room 950 Westwood Building, Telephone: 301-496-7125
Dates of meeting: March 17-18, 1983
Place of meeting: Building 31C, Conference Room 6, National Institutes of Health
Open: March 17, 1983, 8:45 a.m.-10:30 a.m.
Closed: March 17, 1983, 10:30 a.m.-5:00 p.m.; March 18, 1983, 8:30 a.m.-adjournment
Closure reason for each committee: To review research applications

(Catalog of Federal Domestic Assistance Program No. 13-863, 13-860, 13-859, National Institute of General Medical Sciences, National Institutes of Health)

Dated: January 14, 1983.

Betty J. Beveridge,

Committee Management Officer, National Institutes of Health.

[FR Doc. 83-2654 Filed 1-31-83; 8:45 am]

BILLING CODE 4140-01-M

National Institute of Child Health and Human Development, Population Research Committee; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Population Research Committee, National Institute of Child Health and Human Development, on March 10-11, 1983 in the Landow Building, Conference Room "A," 7910 Woodmont Avenue, Bethesda, Maryland.

This meeting will be open to the public on March 10 from 9:00 a.m. to 10.30 a.m to discuss the program status, new developments and projections for population research centers, program projects and institutional fellowships. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Title 5, U.S. Code, Sections 552b(c)(4) and 552b(c)(6) and Section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on March 10 from 10:30 a.m. to adjournment on March 11 for the review, discussion and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Marjorie Neff, Committee Management Officer, NICHD, Landow Building, Room 6C-08, National Institutes of Health, Bethesda, Maryland, Area Code 301, 496-1485, will provide a summary of the meeting and a roster of committee members. Dr. Dinesh C. Sharma, Executive Secretary of the Population Research Committee, NICHD, Landow Building, Room 6C-03, National Institutes of Health, Bethesda, Maryland, Area Code 301, 496-1696, will furnish other information.

(Catalog of Federal Domestic Assistance Program No. 13.864, Population Research, National Institutes of Health)

Dated: January 14, 1983.

Betty J. Beveridge,

Committee Management Officer, National Institutes of Health.

[FR Doc. 83-2653 Filed 1-31-83; 8:45 am]

BILLING CODE 4140-01-M

Subcommittee on Animal Resources of the Animal Resources Review Committee; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Subcommittee on Animal Resources, Animal Resources Review Committee, Division of Research Resources on March 3, 1983 from 1:00 p.m. to recess and on March 4, 1983 from 8:00 a.m. to adjournment in Conference Room 7, Building 31, National Institutes of Health, Bethesda, Maryland 20205.

The meeting will be open to the public on March 4 from approximately 10:00 a.m. to adjournment for a brief staff presentation on the current status of the Animal Resources Program and the selection of future meeting dates. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Sections 552b(c)(4) and