percent of the voting shares of LNB Bancorp, Inc., Lorain, Ohio, and thereby indirectly acquire voting shares of the Lorain National Bank, Lorain, Ohio.

Board of Governors of the Federal Reserve System, December 22, 2005.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E5–7944 Filed 12–27–05; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005P–0244]

Determination That DECADRON (Dexamethasone) Tablets, 1.5 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that DECADRON (dexamethasone) tablets, 1.5 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for dexamethasone tablets, 1.5 mg.

FOR FURTHER INFORMATION CONTACT: Janice L. Weiner, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98–417), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

DECADRON (dexamethasone) tablets, 1.5 mg, are the subject of approved NDA 11–664 held by Merck & Co., Inc. (Merck). According to Merck's 1997 annual report, the 1.5–mg dose strength, among others, of DECADRON (dexamethasone) tablets, a synthetic adrenocortical steroid, was discontinued in 1997. In a citizen petition dated June 16, 2005 (Docket No. 2005P–0244), submitted under 21 CFR 10.30, ECR Pharmaceuticals requested that the agency determine whether DECADRON (dexamethasone) tablets, 1.5 mg, were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Merck's DECADRON (dexamethasone) tablets, 1.5 mg, were not withdrawn from sale for reasons of safety or effectiveness. FDA has reviewed its files for records concerning the withdrawal of DECADRON (dexamethasone) tablets, 1.5 mg, from sale. There is no indication that the decision not to market DECADRON (dexamethasone) tablets, 1.5 mg, commercially is a function of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data for possible concerns regarding the safety or effectiveness of this drug product. FDA has found no information that would indicate that this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that for the reasons outlined previously, DECADRON (dexamethasone) tablets, 1.5 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DECADRON (dexamethasone) tablets, 1.5 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs for dexamethasone tablets, 1.5 mg, that comply with relevant legal and regulatory requirements may be approved by the agency.

Dated: December 19, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E5–7875 Filed 12–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0488]

Animal Drug User Fee Act; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on the Animal Drug User Fee Act (ADUFA) to seek public comments relative to the program's overall performance and reauthorization as directed by Congress.

Date and Time: The public meeting will be held on February 24, 2006, from 9 a.m. to 5 p.m. Requests to make a presentation at the meeting must be received by February 10, 2006. Written comments regarding this meeting may be made by March 26, 2006, to the Division of Dockets Management (see **ADDRESSES**).

Location: The meeting will be held at the DoubleTree Hotel, Plaza II and III, 1750 Rockville Pike, Rockville, MD 20852. Registration is not required to attend the meeting. Parking is limited, so we recommend arriving by subway (Metro rail) if possible. The DoubleTree Hotel is accessible from the Metro rail's red line at the Twinbrook station.

ADDRESSES: You may submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments.

FOR FURTHER INFORMATION CONTACT: Aleta Sindelar, Center for Veterinary

Medicine (CVM) (HFV–3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9004, FAX: 240–276–9020, e-mail: *asindela@cvm.fda.gov*.

Transcripts: Meeting transcripts will be made available on CVM's Web site (*http://www.fda.gov/cvm/adufa.htm*) approximately 30 working days after the meeting. The transcript will also be available for public examination at the Division of Dockets Management (see **ADDRESSES**), between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

In the language authorizing the Animal Drug User Fee Act, Congress directed the Secretary of Health and Human Services (the Secretary) to consult with the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor and Pensions of the Senate, appropriate scientific and academic experts, veterinary professionals, representatives of consumer advocacy groups, and the regulated industry in developing recommendations to Congress for the reauthorization of ADUFA and for the goals and plans for meeting the goals associated with the process for review of animal drug applications. As directed by Congress, FDA is holding a public meeting to gather information on what features we should propose to include in the ADUFA program (*http://www.fda.gov/cvm/4218.htm*) and hear stakeholder views on this subject.

We are offering the following two general questions for consideration, and we are interested in responses to these questions and any other pertinent information stakeholders would like to share:

1. What is your assessment of the overall performance of the ADUFA program thus far?

2. What suggestions or changes would you make relative to the reauthorization of ADUFA?

ADUFA, amended the Federal Food, Drug, and Cosmetic Act (the act) and authorized FDA to collect fees for certain animal drug applications, establishments, products, and sponsors in support of the review of animal drugs. These additional resources support FDA's responsibilities under the act to ensure that new animal drug products are safe and effective for animals as well as for the public with respect to animals intended for food consumption.

FDA's animal drug user fee program was authorized in 2003 and implemented in 2004. A significant part of the preparations for the program included determining the fee levels for fiscal year (FY) 2004. ADUFA provides for the following four fees: (1) A sponsor fee, (2) an establishment fee, (3) a product fee, and (4) an application fee. The act also provides for specific waivers and exemptions from fees. FDA prepared guidance for the industry regarding the fees, billings and submission of fees, and waivers and exemptions (*http://www.fda.gov/cvm/adufa.htm*).

The total amounts of monies expected for collection were as follows: $5 million for FY 2004; $8 million in FY 2005; and, $10 million in each FY 2006 through 2008. Each fee type was expected to be 25 percent of the total amount collected. Thus, in FY 2006, we expect to receive $2,500,000 from sponsor fees, establishment fees, product fees, and application fees, for a total of $10,000,000 dollars (figures are subject to inflation and workload adjustments). The user fees are used to achieve shorter, more predictable review times by increasing the review staff at FDA and building better management systems. As a result, we anticipate substantial savings to the industry in regulatory review and developmental expenses.

FDA's animal drug premarket review program is making continual and substantial improvements in the animal drug review process as a result of user fees. This helps ensure an adequate supply of safe and effective therapeutic and production animal drugs.

We have published a number of reports that may help inform the public about the ADUFA program. Key documents such as ADUFA-related guidance, legislation, performance reports, and financial reports, can be found at *http://www.fda.gov/cvm/adufa.htm*.

II. Meeting

FDA will conduct the meeting on February 24, 2006, at the DoubleTree Hotel (see *Location*). In general, the meeting format will include presentations by FDA and a series of panels representing different stakeholder interest groups (scientific and academic experts, veterinary professionals, representatives of consumer advocacy groups, and the regulated industry). FDA and panel presentations are planned from 9 a.m. until 12 noon. The open public comment portion of the meeting for registered speakers is planned to begin at 1 p.m. An opportunity for public comments from meeting attendees will commence following the registered presentations, if time permits. The docket will remain open for written comments through March 26, 2006, 30 days following the meeting.

If you wish to reserve time to make a presentation at the meeting, please contact Aleta Sindelar (see **FOR FURTHER INFORMATION CONTACT**) by February 10, 2006. Your request to make a presentation should include the following information: Name, company, company address, company phone number, and e-mail address. We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak.

If you require special accommodations due to a disability, please contact the DoubleTree Hotel (see *Location*) at least 7 days in advance of the meeting.

III. Comments

If you would like to submit written comments to the docket regarding ADUFA, please send your comments to the Division of Dockets Management (See **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be reviewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 20, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E5–7876 Filed 12–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children (ACHDGDNC).

Dates and Times: February 13, 2006, 9 a.m. to 5 p.m.; February 14, 2006, 8:30 a.m. to 3 p.m.

Place: Ronald Reagan Building and International Trade Center, Rotunda Room,