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Determination That DECADRON (Dexamethasone) Tablets, 1.5 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Food and Drug Administration (FDA) has determined that DECADRON (dexamethasone) tablets, 1.5 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness.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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the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