Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product STRATTERA (atomoxetine hydrochloride). STRATTERA is indicated for the treatment of attention-deficit/hyperactivity disorder. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for STRATTERA (U.S. Patent No. 5,658,590,) from Eli Lilly & Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 16, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of STRATTERA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for STRATTERA is 7,718 days. Of this time, 7,307 days occurred during the testing phase of the regulatory review period, while 411 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: October 11, 1981. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 11, 1981.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: October 12, 2001. FDA has verified the applicant's claim that the new drug application (NDA) for STRATTERA (NDA 21–411) was initially submitted on October 12, 2001.

3. *The date the application was approved*: November 26, 2002. FDA has verified the applicant's claim that NDA 21–411 was approved on November 26, 2002.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 685 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written comments and ask for a redetermination by February 2, 2004. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 1, 2004. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 30, 2003.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 03–30028 Filed 12–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–03–7000]

Memorandum of Understanding Between the Food and Drug Administration and Agricultural Marketing Service, United States Department of Agriculture

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration and Agricultural Marketing Service, United States Department of Agriculture. The purpose of the MOU is to ensure that sponsors of new antimicrobial animal drugs have access to an effective means for evaluating the effects of their drugs on current Food Safety and Inspection Service detection tests.

DATES: The agreement became effective January 23, 2003.

FOR FURTHER INFORMATION CONTACT: Valerie Reeves, Center for Veterinary Medicine (HFV–151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6973.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108 (c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: November 21, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

225-03-7000

MEMORANDUM OF UNDERSTANDING
Between the
Agricultural Marketing Service
United States Department of Agriculture
and the
Food and Drug Administration
United States Department of Health and Human Services

NAME OF PROJECT: Determination of the Reactivity of New Animal Drugs in Food Safety and Inspection Service (FSIS) Antimicrobial Detection Tests.

OBJECTIVE: The objective of this Memorandum of Understanding (MOU) is to ensure that sponsors of new antimicrobial animal drugs have access to an effective means for evaluating the effects of their drugs on current FSIS detection tests.

FSIS conducts screening and confirmation assays, based on microbial growth inhibition, to detect antimicrobial drug residues in animal tissue used for human food. These assays must be sufficiently reliable because they are important for ensuring food safety. However, new antimicrobial drugs have the potential to interfere with the current assays and FSIS's ability to correctly interpret the results. In addition to FSIS and CVM, manufacturers of antimicrobial animal drugs have an interest in avoiding such interference, particularly when interference causes a test to indicate a false positive. For these reasons, the U.S. Department of Health and Human Services, Food and Drug Administration (FDA) requests that sponsors evaluate the effect of the antimicrobial new animal drugs on the residue detection tests FSIS commonly uses. This information is used in creating strategies to assure the continued reliability of the tests used to monitor food safety.

In FDA's experience, companies that sponsor new animal drugs often do not have ready access to laboratories that can properly evaluate the effects of their drugs on current FSIS detection tests. The Science and Technology Programs of the U.S. Department of Agriculture, Agricultural Marketing Service (AMS), has the ability to perform the necessary evaluation on a fee for service basis. Therefore, FDA and AMS, through this MOU, are agreeing to make that service available to drug sponsors.

EFFECTIVE DATE: Date of final signature.

ORGANIZATION: For AMS, members of the Microbiology Laboratory, USDA, AMS, Eastern Laboratory will perform the analyses, and the Laboratory Director will supervise them. The laboratory analysis will be performed at:

USDA, AMS, Science & Technology
National Science Laboratory
801 Summit Crossing Place, Suite B
Gastonia, North Carolina 28054

AMS contact: Laboratory Director
Phone: 704-867-3873
FAX: 704-853-2800

The FDA office responsible for reviewing the human food safety aspects of new animal drugs is the Center for Veterinary Medicine, Office of New Animal Drug Evaluation, Division of Human Food Safety. This office is located at:

Center for Veterinary Medicine
Division of Human Food Safety (HFV-150)
7500 Standish Place
Rockville, MD 20855

FDA contact: Director, Division of Human Food Safety (HFV-150)
Office of New Animal Drug Evaluation
Center for Veterinary Medicine
Phone: (301) 827-5282
FAX: (301) 827-2298

RESPONSIBILITIES:

A. FDA agrees to:

1. Inform sponsors of new antimicrobial animal drugs that the AMS laboratory is capable of evaluating the effects of those drugs on the FSIS detection tests, and that AMS's role is limited to its evaluation of the effects of new antimicrobial drugs on FSIS detection tests.

2. Inform sponsors of AMS's requirement for:
   a. drug free tissues for control and fortification purposes;
   b. tissues that contain the incurred drug;
   c. sufficient chemically characterized drug standard of the same grade as that used in the manufacture of the drug article; and
   d. the following information about the drug product: chemical name, trade name, active ingredients, dosage form, dose(s) for use in the animal, manufacturing site, lot number or batch number if relevant, drug storage information, packaging information, storage stability and conditions affecting stability, and material safety data sheets.

3. Consider AMS's expertise in evaluating the effects of new antimicrobial animal drugs on FSIS detection tests.

4. If requested by the sponsor, review and comment on the tissues and drug levels proposed to be tested.

B. AMS agrees to:

1. Provide an analytical laboratory capable of performing the analysis specified in the FDA/FSIS protocol *"Determination of the Reactivity of New Animal Drugs in FSIS Antimicrobial Detection Tests"* and described in the *Microbiology Laboratory Guidebook (MLG) 3rd edition*, 1998, Chapter 33, Sections 33.26-33.27; 33.36-33.363; 33.55-33.57; and Chapter 34.

2. Conform its basic protocol outline for testing to the specifications in the FDA/FSIS protocol *"Determination of the Reactivity of New Animal Drugs in FSIS Antimicrobial Detection Tests."*

3. Send the final report of its analytical work to the drug's sponsor.

4. Include in its final report to the drug sponsor the following information:
   a. drug concentrations tested;
   b. buffers used for testing;
   c. tissues tested, specific controls, and fortified and incurred samples;
   d. tissue preparation or extraction procedure;
   e. screening tests used; and
   f. screening test and 7-plate bioassay results for buffer, fortified, and incurred samples, organized by tissue and screening test.

5. Communicate directly with sponsors in regard to the testing of the sponsors' drugs and refer other communications regarding the drug approval process to FDA.

C. It is mutually agreed that:

1. This MOU provides sponsors with one means of evaluating the effects of new antimicrobial animal drugs on the FSIS detection tests, and sponsors retain their discretion in providing this requested information.

2. FDA is not bound by any positions AMS may take as a result of its analysis of a new animal drug pursuant to this MOU. FDA will consider the information provided by AMS as specified in this MOU, but its decisions are independent.

3. Except as otherwise required by law, AMS is not bound by any positions FDA may take as a result of FDA's evaluation of a new animal drug.

4. FDA and AMS will continue to cooperate on improvement of testing protocols as necessary.

BASIS OF COOPERATION/FUNDING:

This MOU defines in general terms the basis on which the parties concerned will cooperate, and does not constitute a financial obligation to serve as a basis for expenditures. Each party will handle and expend its own funds.

Any and all expenditures from Federal funds in the Department of Agriculture made in conformity with the plans outlined in the MOU must be in accord with Department rules and regulations and in each instance based upon appropriate finance papers. Expenditures made by any other cooperator will be in accord with its rules and regulations.

The responsibilities assumed by the cooperating parties under this Memorandum of Understanding are contingent upon funds being available from which expenditures legally may be met.

DURATION:

This agreement shall continue in force indefinitely. It may be amended or terminated by mutual consent of the parties in writing. It may be terminated by either party upon 30 days' notice in writing to the other party.

This agreement is hereby approved for the Agricultural Marketing Service.
On 11/23/03
(Date)

Kenneth C. Clayton
Associate Administrator
Agricultural Marketing Service

This agreement is hereby approved for the Food and Drug Administration.
On 11/13/03
(Date)

Stephen Sundlof, D.V.M., Ph.D.
Director
Center for Veterinary Medicine
Food and Drug Administration

[FR Doc. 03–30027 Filed 12–2–03; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–02–8000]

Memorandum of Understanding Between the Food and Drug Administration and Johns Hopkins University

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a Memorandum of Understanding (MOU) between FDA and Johns Hopkins University. The purpose of the MOU is to develop collaboration in the areas of education, research, and outreach.

DATES: The agreement became effective April 30, 2002.

FOR FURTHER INFORMATION CONTACT: Peter Pitts, Office of External Relations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3330.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108 (c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: November 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S