patent's eligibility for patent term restoration. In a letter dated September 29, 1998, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period, and that the approval of Monostrut™ Cardiac Valve Prosthesis represented the first permitted commercial marketing or use of the product. Shortly 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 Monostrut™ Cardiac Valve Prosthesis is 5,620 days. Of this time, 1,729 days occurred during the testing phase of the regulatory review period, while 3,891 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: May 14, 1982. FDA has verified the applicant's claim that the date the investigational device exemption required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective May 14, 1982.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: February 5, 1987. The applicant claims May 8, 1986, as the date the premarket approval application (PMA) for Monostrut™ Cardiac Valve Prosthesis (PMA P970002) was initially submitted. However, FDA records indicate that PMA P970002 was submitted on February 5, 1987.

3. *The date the application was approved*: September 30, 1997. FDA has verified the applicant's claim that PMA P970002 was approved on September 30, 1997.

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 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 19, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 15, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 4, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–12528 Filed 5–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–99–2001]

Memorandum of Understanding Between the Food and Drug Administration and the 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 FDA and the United States Department of Agriculture, Food Safety and Inspection Service. The purpose of the MOU is to facilitate an exchange of information between the agencies about establishments and operations that are subject to the jurisdiction of both agencies.

DATES: The agreement became effective February 23, 1999.

FOR FURTHER INFORMATION CONTACT: Gary L. Pierce, Office of Regulatory Affairs (HFC–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5655.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20. 108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: May 11, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

BILLING CODE 4160–01–F

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MOU 225-99-2001

MEMORANDUM OF UNDERSTANDING

Between The

FOOD SAFETY AND INSPECTION SERVICE
UNITED STATES DEPARTMENT OF AGRICULTURE

And The

FOOD AND DRUG ADMINISTRATION
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

I. PURPOSE

This agreement between the Food and Drug Administration, Department of Health and Human Services (FDA) and the Food Safety and Inspection Service, United States Department of Agriculture (FSIS), is intended to facilitate an exchange of information between the agencies about establishments and operations that are subject to the jurisdiction of both agencies. This exchange of information will permit more efficient use of both agencies' resources and will contribute to improved public health protection.

II. BACKGROUND

In a May 1997 Report to the President entitled "Food Safety From Farm to Table - A National Food-Safety Initiative," the agencies primarily responsible for food safety made several recommendations to improve public health protection from foodborne illness. Several recommendations addressed the issues of increasing cooperation among agencies and, more specifically, of ensuring that the resources and experience of FDA and FSIS are used as efficiently as possible to avoid duplication of efforts.

To advance the purposes of the President's Food Safety Initiative, FDA and FSIS have re-evaluated a previous Memorandum of Understanding on coordination of inspectional efforts signed by FSIS on July 14, 1983 and by FDA on July 25, 1983. The agencies have determined that changes in inspectional activities, available resources, and food safety hazards necessitate updating that agreement. Therefore, FDA and FSIS have entered into this Memorandum of Understanding to address today's public health needs.

III. STATUTORY AUTHORITIES

FSIS is responsible for implementing and enforcing the Federal Meat Inspection Act (21 U.S.C.

601, *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451, *et seq.*), and parts of the Egg Products Inspection Act (21 U.S.C. 1031, *et. seq.*). In carrying out its responsibilities under these acts, FSIS places inspectors in meat and poultry slaughterhouses and in meat, poultry, and egg processing plants. FSIS also conducts inspections of warehouses, transporters, retail stores, restaurants, and other places where meat, poultry, and egg products are handled and stored. In addition, FSIS conducts voluntary inspections under the Agriculture Marketing Act (7 U.S.C. 1621, *et seq.*).

FDA is responsible for implementing and enforcing the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, *et seq.*), the Public Health Service Act (42 U.S.C. 201, *et. seq*), the Fair Packaging and Labeling Act (15 U.S.C. 1451 *et. seq),* and parts of the Egg Products Inspection Act. In carrying out its responsibilities under these acts, FDA conducts inspections of establishments that manufacture, process, pack, or hold foods, with the exception of certain establishments that are regulated exclusively by FSIS. FDA also inspects vehicles and other conveyances, such as boats, trains, and airplanes, in which foods are transported or held in interstate commerce.

Nothing in this agreement shall lessen the responsibilities or authorities of FSIS or FDA under their statutory authorities.

IV. SUBSTANCE OF AGREEMENT

1. List of District Level Contacts

The agencies agree to develop, maintain, and annually update a list of their districts and of persons to contact at the district management level. In addition to the annual updates to these lists, each district agrees to promptly inform its counterpart district of any change in the contact person for that district. The agencies also agree to develop and maintain a list of the district offices responsible for each state and territory. Each agency agrees to promptly inform the other agency of any changes in the jurisdiction of district offices or in the field organization of the agency. These lists are to be distributed to the district managers of both FSIS and FDA.

2. List of Dual Jurisdiction Establishments

The agencies agree to develop, maintain, and annually update a list of dual jurisdiction establishments (hereinafter "DJEs"), that is, establishments that prepare, pack, hold, or otherwise handle both foods regulated by FSIS and foods regulated by FDA. This list is to be organized by state and territory and will be distributed to the district managers of both FSIS and FDA. When updating this list, each agency agrees to identify all DJEs that have discontinued operations that are under its jurisdiction.

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3. System of Communication

The district offices of each agency agree to promptly report to their counterpart district offices certain findings, as set forth in paragraphs 5, 6, and 7, relating to DJEs. The district office receiving the report agrees to respond with information regarding any planned or completed follow-up action relating to the reported information. District management of both agencies are encouraged to initiate contact and to meet annually, or as frequently as necessary, to facilitate the exchange of information about establishments and foods prepared, packed, held, or otherwise handled by these establishments. The agencies agree to work together to develop, put in place, and maintain a system of electronic communication at the district level to facilitate the exchange of information about the DJEs.

4. Notification of Periodic Inspection

Each agency agrees to attempt to notify the appropriate contact identified in paragraph 1 of this section prior to conducting an inspection of a DJE that is not under continuous FSIS inspection. In addition, FDA agrees to attempt to notify the FSIS inspector prior to inspecting a DJE that is under continuous inspection and to invite the FSIS inspector to accompany the FDA investigator on the inspection.

5. Findings Involving DJEs That Are To Be Reported By Both Agencies

The district office of each agency is to notify its counterpart district office of the following findings in a DJE:

a. Foods implicated in outbreaks of foodborne illness, injuries, or adverse reactions.

b. Foods found to be contaminated or mislabeled such that there is a reasonable probability that the use of or exposure to such products will cause serious adverse health consequences. Hazards that constitute contamination or mislabeling covered under this paragraph are attached as Appendix A.

c. A processing condition or failure that is likely to result in food contamination leading to outbreaks of foodborne illness, injuries, or adverse reactions.

d. Foods that have been recalled.

e. Reports of tampering or threats of tampering.

f. A food handler diagnosed as having a communicable disease that is likely to result in food contamination or outbreaks of foodborne illness (e.g., hepatitis).

g. Convictions of a DJE, or any officer or key employee of a DJE, for any felony or more

than one misdemeanor involving the DJE or any food prepared, packed, held, or otherwise handled in the DJE.

h. Convictions of an establishment preparing, packing, holding, or otherwise handling meat, poultry or egg products solely under state regulation and foods regulated by FDA, or any officer or key employee of such an establishment, for any felony or more than one misdemeanor involving the establishment or any food prepared, packed, held, or otherwise handled in the establishment.

6. Additional Findings Involving DJEs That Are To Be Reported By FSIS to FDA

In addition to the findings in paragraph 5, the FSIS district office is to notify its counterpart district office of FDA of the following finding in a DJE:

a. FSIS action to withhold the mark of inspection or to suspend or withdraw the grant of inspection.

7. Additional Findings Involving DJEs That Are To Be Reported By FDA to FSIS

In addition to the findings in paragraph 5, the FDA district office is to notify its counterpart district office of FSIS of the following findings:

a. Any other processing condition in a DJE that could render foods bearing a USDA mark of mandatory or voluntary inspection adulterated or mislabeled.

b. Reason to believe that an FDA-regulated ingredient that would adulterate a meat, poultry, or egg product if used in it has been sent to or received by an FSIS-regulated establishment.

8. Follow-Up Action

a. The agency receiving notification of a finding listed in paragraphs 5, 6, or 7 agrees to evaluate it and take appropriate action.

b. For all reported findings listed in paragraphs 5, 6, or 7, the agency receiving the notification agrees to track and use the information in program evaluation, work planning, and consideration of whether action against the establishment is warranted.

c. The agency receiving the notification of a finding listed in paragraphs 5, 6, or 7 agrees to respond to the notification within 30 days by communicating the disposition of the notification to the notifying agency at the district management level, including, if appropriate, any and all actions planned and taken by the agency receiving notification. In addition, the agencies agree to explore the feasibility of granting each other access to

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appropriate computer monitoring systems to permit interagency tracking of findings listed in paragraphs 5, 6, or 7.

9. Information Sharing and Confidentiality

To promote increased cooperation and efficient use of enforcement resources, each agency agrees to share information for enforcement purposes upon request by the other agency, to the extent permitted by applicable law. All non-public information shared between the two agencies pursuant to this agreement is subject to all applicable limitations established by statute or regulation on interagency sharing of information. The current policies and procedures for sharing such information are attached as Appendix B.

10. Training

The agencies agree to develop and provide appropriate training in the inspectional techniques and processes of each agency as the agencies determine is necessary to ensure that the contacts for each agency have an appropriate understanding of the workings of the other agency. This understanding will help ensure the successful implementation of this agreement. The agencies agree to develop and initiate the training as quickly as possible. The district managers of both agencies are encouraged to evaluate training needs during annual meetings, or as frequently as necessary, to determine whether additional training is warranted.

11. Joint Enforcement Activities

The agencies agree to establish a group to explore the feasibility of joint enforcement activities. This group is to report its findings and recommendations by March 1, 1999 to the Commissioner of FDA and the Administrator of FSIS.

12. Re-evaluation of the Agreement

The agencies agree to re-evaluate the effectiveness of this agreement after it has been in effect for one year. The agencies also agree to explore the feasibility of expanding their cooperative activities after one year, or sooner if the agencies agree that it is appropriate to do so.

V. PERIOD OF AGREEMENT

The agencies agree to begin implementing this agreement within 30 days from execution by both parties. This agreement will be effective indefinitely. It may be modified by mutual consent or terminated by either party upon 30 days' written notice to the other.

VI. PREVIOUS AGREEMENTS

This agreement supersedes the Memorandum of Understanding on coordination of inspectional

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efforts signed by FSIS on July 14, 1983 and by FDA on July 25, 1983. This MOU does not modify any other existing agreements between USDA and FDA.

VII. NAME AND ADDRESS OF PARTICIPATING AGENCIES

Food Safety and Inspection Service
1400 Independence Ave., S.W.
Washington, DC 20250-3700

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

VIII. LIAISON OFFICERS

For FSIS:
John McCutcheon
Associate Deputy Administrator,
Office of Field Operations
Food Safety Inspection Service
1400 Independence Ave., S.W.
Washington, DC 20250-3700
(202) 720-5190

For FDA:
Gary Pierce
Director, Division of Emergency and
Investigational Operations
Food and Drug Administration
5600 Fishers Lane (HFC-130)
Rockville, MD 20857
(301) 827-5655

APPROVED AND ACCEPTED FOR THE FOOD SAFETY INSPECTION SERVICE

By: _____
Thomas J. Billy

Title: Administrator, FSIS

Date: FEB 23 1999

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

By: _____
Michael A. Friedman, M.D.

Title: Deputy Commissioner
For Operations, FDA

Date: FEB 23 1999

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Appendix A
Findings That Constitute Contamination or Mislabeling Under Section IV, 5, b.

The following findings of contamination or mislabeling should be reported by FSIS to FDA under section IV, 5, b:

1. pathogenic organisms

2. undeclared allergens (e.g., peanuts, peanut butter, peanut flour, hydrolyzed peanut protein, pecans, walnuts, hazelnuts, filberts, cashews, Brazil nuts, eggs, egg whites, egg yolk, egg albumen, powdered eggs, shrimp, crab, crayfish, lobster, oysters, clams, scallops, mussels, almonds, pistachios, cow milk, cream, dry milk, whey, other proteins from cow's milk, soy, soybeans, soy protein, soy flour, corn, corn flour, corn meal, fish, oats, wheat);

3. undeclared color additives FD&C Yellow No. 5 and FD&C Yellow No. 6; and

4. undeclared sulfites.

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Appendix B
Policies and Procedures for Information Sharing

Under this MOU, neither FDA nor FSIS will disclose to each other confidential commercial or trade secret information. The information FDA and FSIS disclose to each other under this MOU may include other information exempt from public disclosure, such as information compiled for law enforcement purposes and predecisional information.

To promote the sharing of information for enforcement purposes, while ensuring that both agencies protect information exempt from public disclosure, FDA and FSIS agree to comply with the following conditions:

1. The agency that shares information ("the information-sharing agency") shall include a transmittal letter along with any non-electronic agency records exchanged that are exempt from public disclosure. A model transmittal letter is attached. The first page of each document provided shall be stamped "CONFIDENTIAL [name of information-sharing agency] DOCUMENTS: DO NOT DISCLOSE WITHOUT WRITTEN PERMISSION OF [name of information-sharing agency]." Electronic records, such as e-mails, that are exchanged and that contain information exempt from public disclosure shall include the following statement: "This e-mail contains information exempt from public disclosure that is being shared in accordance with the Memorandum of Understanding dated January 22, 1999, between FDA and FSIS regarding dual-jurisdiction establishments. This information may not be further disclosed without prior written permission from the agency that provided it."

2. The agency that receives the information ("the recipient agency") shall not disclose any shared information designated by the information-sharing agency as exempt from public disclosure to any person or entity outside the recipient agency, including the Department of Justice or a court, without first requesting and obtaining the written permission of the information-sharing agency. The information-sharing agency will not withhold permission to disclose information pursuant to a court order, provided that the recipient agency notifies the information-sharing agency upon receipt of the order as provided in paragraph 4.

3. The recipient agency shall notify the information-sharing agency upon receipt of any request from a third party for shared information designated by the information sharing agency as exempt from public disclosure. In addition to its ordinary English meaning, the term "request" includes Freedom of Information Act requests, Congressional inquiries, and attempts to obtain information by compulsory process, including, but not limited to, subpoenas and discovery requests.

4. The recipient agency shall notify the information-sharing agency upon receipt of any judicial order that compels the release of shared information designated by the information-sharing agency as exempt from public disclosure so that the information-sharing agency may take appropriate measures, such as filing a motion with the court that issued the order or filing an appeal.

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Model Transmittal Letter

This letter accompanies agency records that are being shared in accordance with the Memorandum of Understanding dated January 22, 1999, between FDA and FSIS regarding dual-jurisdiction establishments. These agency records contain information exempt from public disclosure and may not be further disclosed without prior written permission from the agency that provided them.

[FR Doc. 99–12530 Filed 5–18–99; 8:45 am]
BILLING CODE 4160–01–C