Dated: December 20, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–33369 Filed 12–28–00; 8:45 am]

BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Arrangement Between the United States Food and Drug Administration and Therapeutic Goods Administration, Republic of Australia Regarding the Exchange of Information on Current Good Manufacturing Practice Inspections of Human Pharmaceutical Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of cooperative arrangement between the Food and Drug Administration, Department of Health and Human Services, United States of America and the Therapeutic Goods Administration, Department of Health and Aged Care, Commonwealth of Australia. The purpose of the arrangement is to enable each administration to obtain information that will enable it to make its own independent facility and/or product regulatory decisions in the assessment of current good manufacturing practices compliance, public health protection, and approval of new drugs. It also will facilitate more efficient use of resources for each organization in meeting their statutory requirements without reduction of public safety or regulatory responsibilities.

DATES: The arrangement became effective October 11, 2000.

FOR FURTHER INFORMATION CONTACT: Merton V. Smith, Office of International Programs, International Agreements Staff (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0910.

SUPPLEMENTARY INFORMATION: This cooperative arrangement is subject to FDA's regulations in 21 CFR 20.108 for cooperative agreements. Therefore, 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 written arrangement.

Dated: December 20, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

The arrangement is set forth in its entirety as follows:

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COOPERATIVE ARRANGEMENT

BETWEEN THE

FOOD AND DRUG ADMINISTRATION

OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OF THE

UNITED STATES OF AMERICA

AND THE

THERAPEUTIC GOODS ADMINISTRATION

OF THE

DEPARTMENT OF HEALTH AND AGED CARE

OF THE

COMMONWEALTH OF AUSTRALIA

REGARDING THE EXCHANGE OF INFORMATION ON

CURRENT GOOD MANUFACTURING PRACTICE INSPECTIONS

OF HUMAN PHARMACEUTICAL FACILITIES

The Food and Drug Administration, Department of Health and Human Services (FDA) of the United States of America and the Therapeutic Goods Administration, Department of Health and Aged Care (TGA) of the Commonwealth of Australia in order to exchange information and/or documents on the observations and results of inspections of human pharmaceutical products and facilities for adherence to Current Good Manufacturing Practices (CGMPs) and conditions of adulteration, misbranding, or adverse health consequences;

Recognizing that this Arrangement provides the means by which each Administration can obtain information that will enable it to make its own independent facility and/or product

regulatory decisions in the assessment of CGMP compliance, public health protection and approval of new drugs; and,

Realizing that this Arrangement can save both time and costs for each Administration in meeting their statutory requirements without reduction of public safety or regulatory responsibilities;

Hereby jointly plan to undertake the activities as stated herein.

A. For FDA:

1. Upon request from the TGA, FDA intends to promptly furnish copies of pharmaceutical establishment inspection reports and product sample results prepared by FDA employees.

2. In response to a request from the TGA, the FDA will endeavor to reinspect and provide a written inspection report, normally within 90 days, on a specific pharmaceutical facility in which current FDA information on CGMP compliance does not exist to determine the acceptability of CGMP compliance for the same profile class as that of the TGA request. Any such inspections of pharmaceutical plants conducted by the FDA in the United States will be conducted in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

3. In those cases where a hazard to health is reported by the TGA and concurred in by the FDA, FDA intends to conduct an inspection in an expedited manner to provide the TGA with the written inspection/investigation report.

4. In those cases related to a request to inspect a specific drug product, FDA will endeavor to perform the inspection normally within a period of 45 days. If an inspection cannot be performed or cannot be performed within this time frame, FDA plans to notify TGA within 15 days of the request.

5. FDA intends to notify the TGA as soon as practical that it plans to conduct a CGMP inspection in Australia. FDA intends to be receptive to authorized inspectors of the TGA accompanying FDA employees in an effort to promote better understanding of FDA's inspectional programs and techniques.

6. FDA will endeavor to provide the TGA with prompt notification to manufacturing conditions and/or particular products, which may constitute a potential hazard to health or significant violations of CGMPs. This may include the exchange of recall information, adverse product trends, health hazard evaluations, and alert system(s) information deemed appropriate by the FDA.

7. FDA plans to continue to allow the TGA access to facility/profile class approval status listing in its computer databases (COMSTAT).

8. FDA will endeavor to provide assistance to TGA when drug shortage situations involving medically necessary human pharmaceuticals occur in Australia by providing information regarding manufacturers of these pharmaceuticals to or in the United States and the regulatory status of these manufacturers when possible.

9. To the extent funding resources allow and by joint agreement, the FDA will endeavor to arrange for meetings at least once per year between its inspectors/investigators, technical experts, compliance officers, and/or management employees and those of the TGA for the purpose of developing and reviewing inspectional techniques, computer databases, report formats, guidance documents, and laws and/or regulations in an effort to enhance harmonization between the FDA and TGA.

10. FDA intends to provide information under this Arrangement according to relevant U.S. laws and regulations. FDA intends to generally provide information that is publicly available under U.S. law and regulations. Where TGA needs and requests non-public information, FDA intends to provide such information in accordance with Part 20 of Title 21 of the U.S. Code of Federal Regulations.

FDA intends to protect from public disclosure information it receives from TGA pursuant to this Arrangement to the extent required or permitted under U.S. law and regulations.

FDA intends to use the information it receives from TGA to assess the compliance of human pharmaceutical facilities or products manufactured, distributed, or offered for distribution within the United States or its territories.

11. FDA intends to identify to the TGA appropriate individuals/offices as the primary liaison officer for this Arrangement and as contact points for the activities to be carried out under this Arrangement with regard to inspection notifications, sample/inspection report requests and compliance actions, recalls/alerts/adverse event reports, drug shortages, and meetings.

B. For TGA:

1. Upon request from the FDA, TGA intends to promptly furnish FDA with copies of pharmaceutical establishment inspection reports and product sample results prepared by TGA employees.

2. In response to a request from the FDA, the TGA will endeavor to re-inspect and provide a written inspection report, normally within 90 days, on a specific pharmaceutical facility in which current TGA information on CGMP compliance does not exist to determine the acceptability of CGMP compliance for the same profile class as that of the FDA request. Any such inspections of pharmaceutical facilities in Australia will be conducted by the TGA in accordance with the requirements of the Therapeutic Goods Act, 1989, and its implementing regulations.

3. In those cases where a hazard to health is reported by the FDA, and concurred with by the TGA, TGA intends to conduct an inspection in an expedited manner to provide the FDA with the written inspection/investigation report.

4. In those cases related to a request to inspect a specific drug product, TGA will endeavor to perform an inspection normally within a period of 45 days. If an inspection cannot be performed or performed within this time frame,TGA intends to notify FDA within 15 days of the request.

5. TGA intends to notify FDA as soon as practical that it plans to conduct a CGMP inspection in the U.S. or its territories. TGA intends to be receptive to authorized investigators of the FDA accompanying TGA employees in an effort to promote better understanding of TGA's inspectional programs and techniques.

6. TGA will endeavor to provide the FDA with prompt notification of manufacturing conditions and/or particular products which may constitute a potential hazard to health or significant violations of CGMPs. This may include the exchange of recall information, adverse product trends, health hazard evaluations, and alert system(s) information deemed appropriate by the TGA.

7. TGA intends to provide FDA access to information on facility approval status, including the product categories involved, in its computer databases and/or through hard copy records where no computer data exists.

8. TGA will endeavor to provide assistance to FDA when drug shortage situations involving medically necessary human pharmaceuticals occur in the U.S. by providing information regarding manufacturers of these pharmaceuticals to or in Australia and the regulatory status of these manufacturers when possible.

9. To the extent funding resources allow and by joint agreement, the TGA will endeavor to arrange for meetings between its inspectors/investigators, technical experts, compliance officers, management employees and those of the

FDA for the purpose of developing and/or reviewing inspectional techniques, computer databases, report formats, guidance documents, and laws and/or regulations in an effort to enhance harmonization between both FDA and TGA.

10. TGA intends to provide information pursuant to this Arrangement in confidence to FDA in accordance with Australian law. TGA will protect information received from FDA to the extent allowed under Australian law. TGA intends to use information it receives from the FDA only to assess the compliance of human pharmaceutical facilities or products manufactured, distributed, or offered for distribution within the Commonwealth of Australia.

11. TGA intends to identify to the FDA the appropriate individuals/offices as primary liaison officer for this Arrangement and as contact points for this Arrangement with regard to inspection notifications, sample/inspection report requests/compliance actions, recalls/alerts/adverse event reports, drug shortages, and meetings.

PERIOD OF COOPERATIVE ARRANGEMENT

This Arrangement enters into force upon signing by both Administration representatives and continues in effect for a period of five (5) years unless modified by mutual consent of both parties or termination earlier by either party upon written notification.

This Arrangement does not modify existing arrangements nor does it preclude entering into separate arrangements for special programs which can be handled more efficiently and expeditiously by special arrangements.

Nothing in this Arrangement is intended to diminish or otherwise affect the authority of either agency (FDA/TGA) to carry out its respective statutory functions. Additionally, no provision of this Arrangement restricts either administration from making its own inspection of any pharmaceutical facility located within the jurisdictional boundaries of the other country when needed to meet the needs of its own drug regulatory program.

FOR THE FOOD AND DRUG ADMINISTRATION, DEPARTMENT HEALTH AND HUMAN SERVICES OF UNITED STATES OF AMERICA

DATE: October 11, 2000
PLACE: Rockville, Maryland

FOR THE THERAPEUTIC GOODS ADMINISTRATION, DEPARTMENT OF HEALTH AND AGED CARE OF COMMONWEALTH OF AUSTRALIA

DATE: 11.10.00
PLACE: Rockville MD

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