Dated: January 15, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–1481 Filed 1–21–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0003]

Dulal C. Chatterji; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Mr. Dulal C. Chatterji, 8025 Cobble Creek Circle, Potomac, MD 20854, from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Chatterji was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Chatterji has notified FDA that he acquiesces to debarment and, therefore, has waived his opportunity for a hearing concerning this action.

EFFECTIVE DATE: November 1, 1995.

ADDRESSES: Application for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

Mr. Dulal C. Chatterji, formerly vice-president for scientific affairs and head of the research and development (R&D) division at Quad Pharmaceuticals, Inc. (Quad), pled guilty to, and on May 12, 1994, was sentenced for, obstructing an agency proceeding, a Federal felony under 18 U.S.C. 1505. The basis for this conviction was as follows:

In its new drug application (NDA) for colistimethate sodium, Quad falsely represented to FDA that it had produced three sterile batches of the drug. In fact, the firm had produced two nonsterile batches and only one sterile batch. During a subsequent FDA audit of Quad's R&D department, Mr. Chatterji directed that samples from the nonsterile batches of colistimethate sodium be destroyed.

Mr. Chatterji is subject to debarment based on a finding, under section 306(a) of the act (21 U.S.C. 355a(a)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Mr. Chatterji's conduct related to the regulation of a drug product because, in causing the destruction of drug samples, he obstructed FDA's investigation of fraudulent NDA data submitted by Quad.

In a letter received by FDA on November 1, 1995, Mr. Chatterji notified FDA of his acquiescence to debarment, as provided for in section 306(c)(2)(B) of the act. A person subject to debarment is entitled to an opportunity for an agency hearing on disputed issues of material fact under section 306(i) of the act, but by acquiescing to debarment, Mr. Chatterji waived his opportunity for a hearing and any contentions concerning his debarment.

II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.99), finds that Mr. Dulal C. Chatterji has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing findings and based on his notification of acquiescence, Mr. Dulal C. Chatterji is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective November 1, 1995, the date of notification of acquiescence (sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Chatterji, in any capacity, during his period of debarment, will be subject to civil money penalties. If Mr. Chatterji, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications (ANDA's) submitted by or with the assistance of Mr. Chatterji during his period of debarment.

Any application by Mr. Chatterji for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 96N–0003 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 7, 1997.

Janet Woodcock

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–1477 Filed 1–21–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 91N–0404]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information regarding Medical Devices, Humanitarian Use Devices has been approved by the Office of Management and Budget (OMB), under the Paperwork Reduction Act of 1995. This document announces the OMB approval number.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–80), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 29, 1996 (61 FR 55804), the agency announced that the proposed information collection requirements on medical devices, humanitarian use devices (21 CFR 814.102, 814.104, 814.106. 814.108, 814.110(a), 814.112(b), 814.116(b), 814.118(d), 814.120(b), 814.124(b), 814.126(b)(i) and (ii)) had been submitted to OMB for review and clearance. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB has approved the collection of information and assigned OMB control number 0910–0332. The approval expires on November 30, 1999. Under 5 CFR 1320.5(b), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.

Dated: January 15, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–1482 Filed 1–21–97; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement (CRADA) for Partnering, Informatics and Technology Development

AGENCY: National Cancer Institute, National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (DHHS) seeks a company that can collaboratively pursue development of an expert, information based system of technology development and transfer. In particular, the Office of Technology Development (''OTD''), National Cancer Institute seeks to co-develop a system for modeling current OTD processes. The system will be tested using both the selected collaborator's processes and outcomes and real-time OTD experiences.

ADDRESSES: Questions about this opportunity may be addressed to William Cotreau, J.D., or Jeremy A. Cubert, M.S., J.D., Office of Technology Development, NCI, 6120 Executive Blvd., MSC 7182, Bethesda, MD 20892–7182, Phone: (301) 496–0477, Facsimile: (301) 402–2117. from whom further information may be obtained.

DATES: In view of the important priority of developing a technology informatics system, interested parties should notify this office in writing no later than March 10, 1997. Respondents will then be provided an additional 30 days for the filing of formal proposals.

SUPPLEMENTARY INFORMATION: ''Cooperative Research and Development Agreement'' or ''CRADA'' means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and amendments (including 104 P.L. 133) and Executive Order 12591 of October 10, 1987 to collaborate on the specific research project described below.

The Office of Technology Development (OTD) serves as the Institute focal point for the implementation of the Federal Technology Transfer Act of 1986. The OTD provides advice, guidance and assistance to Institute staff on such things as: the development and management of intellectual property; registration and management of patents; terms and negotiation of licensing and research and development agreements; management and administration of royalties; transfer of research material; interpretation of laws, policies, rules and regulations especially related to the implementation of the Federal Technology Transfer Act; and other related matters.

The Government is seeking a partner with which, in accordance with the requirements of the regulations governing the transfer of technology in which the Government has taken an active role in developing (37 CFR 404.8), can co-develop a system for modeling technology development processes using information technologies. The National Cancer Institute will provide access to its knowledge and skill base, information regarding current processes and a test bed of technologies not subject to confidentiality obligations. The selected Collaborator will provide expertise in Technology Development, current processes and market awareness.

The expected duration of the CRADA will be two (2) to five (5) years.

The role of the National Cancer Institute, includes the following:

(1) demonstrate current technology development processes related to transactional research agreements.

(2) proof model/equations for logical structure.

(3) provide/input historical NCI–OTD data that are not subject to any confidentiality obligation(s) or where necessary ensure appropriate provisions of confidentiality are applied.

(4) input collaborator historical data.

(5) review model for logical structure.

(6) provide current examples that are not subject to confidentiality obligation(s) or where necessary ensure appropriate provisions of confidentiality are applied in order to further test model.

The role of the collaborator company, includes the following:

(1) program model of NCI current processes related to transactional research agreements.

(2) provide input and feedback regarding NCI processes related to transactional research agreements.

(3) amend model based on feedback from NCI and Collaborator.

(4) provide sufficient information about Collaborator technology development processes to elucidate and improve model.

(5) revise model as necessary.

(6) jointly test model using current NCI technology that is not subject to confidentiality obligation(s) as examples or where necessary ensure appropriate provisions of confidentiality are applied.

(7) develop commercial version of technology development information system.

(8) provide resources as necessary.

Dated: January 8, 1997.

Thomas D. Mays,

Director, Office of Technology Development, OIM, NCI.

[FR Doc. 97–1533 Filed 1–21–97; 8:45 am]

BILLING CODE 4140–10–M

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development.

ADDRESSES: Licensing information and a copy of the U.S. patent application referenced below may be obtained by contacting George H. Keller, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7735 ext. 246; fax 301/402–0220). A signed Confidential Disclosure Agreement will be required to receive a copy of the patent application.

Hepatitis A Virus Receptor and Methods of Use

G Kaplan, SM Feinstone (FDA)

Serial No. 08/287,001 filed 05 Aug 94

This invention describes the discovery and isolation of HAVcr–1, a simian cellular receptor for the hepatitis A virus (HAV). Cells nonpermissive to HAV infection transfected with HAVcr–1 cDNA, a novel cell surface mucin-like glycoprotein, gain susceptibility to HAV infection. The invention claims nucleic acids encoding cellular receptors to HAV which hybridize with HAVcr–1 probes. The invention also claims peptides encoded by the above-mentioned HAV receptor nucleic acid.

Potential areas of application include use of HAVcr–1 receptors for diagnostics; use of HAVcr–1 receptors for treatment of patients infected with HAV; development of compounds capable of interacting with HAVcr–1 receptors which could inhibit HAV