4.*Implementation guidelines:* These practices are in compliance with the standards of chapter 45–13 of the HHS General Administration Manual, ''Safeguarding Records Contained in Systems of Records,'' supplementary Chapter PHS hf: 45–13, and the Department's Automated Information System Security Handbook.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the FDA Records Control Schedule transmittal number H:90–1, Departmental number B–331.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Inspections and Surveillance (HFM–650), Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, 1401 Rockville Pike, Rockville, MD 20852.

Director, Division of Bioresearch Monitoring (HFZ–310), Office of Compliance, Center for Devices and Radiological Health, 2094 Gaither Rd., Rockville, MD 20850.

Deputy Director, Division of Scientific Investigation (HFD–341), Center for Drug Evaluation and Research, Office of Compliance, 7520 Standish Pl., Rockville, MD 20855.

Bioresearch Monitoring Project Manager (HFS–207), Center for Food Safety and Applied Nutrition, Office of Premarket Approval, Division of Product Policy, 200 C St. SW., Washington, DC 20204.

Manager, Bioresearch Monitoring Program (HFV–234), Center for Veterinary Medicine, Division of Compliance, 7500 Standish Pl., Rockville, MD 20855.

NOTIFICATION PROCEDURES:

An individual may learn if a record exists about him or her upon written request with notarized signature or certification of identification under penalty of perjury if request is made by mail, or with identification if request is made in person (see also 21 CFR 21.44), directed to:

FDA Privacy Act Coordinator (HFI–30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Access to record systems which have been granted an exemption from the Privacy Act access requirement may be made at the discretion of the system manager. If access is denied to requested records, an appeal may be made to:

Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

You may also request an accounting of disclosures that have been made of your record, if any.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under notification procedures above and reasonably identify the record, specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Individual on whom the record is maintained. Some material is obtained from third parties, e.g., drug companies, publications, or is developed by FDA.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

This system is exempt from access and contest and certain other provisions of the Privacy Act (5 U.S.C. 552a(c)(3), (d)(1) to (d)(4), (e)(3), (e)(4)(G) to (e)(4)(H) and (f)) to the extent that it includes investigatory material compiled for law enforcement purposes, where access would be likely to prejudice the conduct of the investigation.

[FR Doc. 98–27937 Filed 10–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0135]

Agency Information Collection Activities; Announcement of OMB Approval; OTC Test Sample Collection Systems for Drugs of Abuse Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''OTC Test Sample Collection Systems for Drugs of Abuse Testing'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 5, 1998 (63 FR 10792), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0368. The approval expires on April 30, 2001.

Dated: October 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–27887 Filed 10–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0514]

Draft Guidance for Industry on ANDA's: Impurities in Drug Substances; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until November 23, 1998, the comment period for the draft guidance for industry entitled ''ANDA's: Impurities in Drug Substances.'' FDA published a notice of availability of the draft guidance in the **Federal Register** of July 24, 1998 (63 FR 39880). FDA is taking this action in response to several requests for an extension.

DATES: Written comments on the draft guidance may be submitted by November 23, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft

guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Robert W. Trimmer, Office of Generic Drugs, Center for Drug Evaluation and Research (HFD–625), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855–2737, 301–827–5848.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 24, 1998 (63 FR 39880), FDA published a notice announcing the availability of a draft guidance for industry entitled ''ANDA's: Impurities in Drug Substances.'' The draft guidance provides recommendations for including information in abbreviated new drug applications and supporting drug master files on the content and qualification of impurities in drug substances produced by chemical syntheses for both monograph and nonmonograph drug substances. Interested persons were given until September 22, 1998, to submit written comments on the draft guidance.

On August 4, 1998, FDA received a letter from Perrigo requesting that the agency extend the comment period on the draft guidance 120 days. On August 10, 1998, FDA received a letter from the National Association of Pharmaceutical Manufacturers requesting that the agency extend the comment period on the draft guidance 60 days. On September 4, 1998, FDA received a letter from the Generic Pharmaceutical Industry Association requesting that the agency extend the comment period on the draft guidance 60 days.

This draft guidance is complex and introduces a number of new issues. Therefore, the agency has decided to reopen the comment period on the draft guidance until November 23, 1998, to allow the public more time to review and comment on its contents.

Interested persons may, on or before November 23, 1998, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments 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. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–27888 Filed 10–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Opportunities for Cooperative Research and Development Agreements

National Cancer Institute: Opportunities for Cooperative Research and Development Agreements (CRADAs) for the identification of analogues of wnt ligands that bind a novel soluble Frizzled-related receptor discovered at the National Cancer Institute (NCI) (the ''Technology''). Wnt proteins act as inducing agents during embryogenesis and have been implicated in the etiology of cancer. Frizzled proteins are integral membrane proteins that recently were shown to function as receptors for wnt signaling molecules. Currently, NCI has identified at least two applications for this Technology: research product and drug screening. The NCI is looking for a CRADA Collaborator with access to phage display peptide libraries for analogue screening to develop this Technology.

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. § 3710; Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer and Advancement Act of 1995), the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHSS) seeks one or more CRADAs with pharmaceutical or biotechnology companies to develop this Technology.

Any CRADA for the biomedical use of this technology will be considered. The CRADA would have an expected duration of one (1) to five (5) years. The goals of the CRADA include the rapid publication of research results and the timely commercialization of products, diagnostics and treatments that result from the research. The CRADA Collaborator will have an option to negotiate the terms of an exclusive or nonexclusive commercialization license to subject inventions arising under the CRADA.

ADDRESSES: Proposals and questions about these CRADA opportunities may be addressed to Vasant T. Gandhi, Technology Development and Commercialization Branch, National Cancer Institute, Executive Plaza South, Room 450, 6120 Executive Blvd., Rockville, MD 20852. Telephone: (301) 496–0477, Facsimile: (301) 402–2117. Background information, including abstracts and reprints, is available. In addition, pertinent information not yet publicly disclosed may be obtained under a confidential disclosure agreement.

EFFECTIVE DATE: In view of the high interest for developing the Technology, interested parties should notify the NCI Technology Development and Commercialization Branch in writing no later than November 18, 1998. Respondents will then be provided an additional thirty (30) days for submitting formal CRADA proposals.

SUPPLEMENTARY INFORMATION: A novel Frizzled-related soluble receptor has been expressed recombinantly and used in an ELISA format to bind protein ligand. The NCI Laboratory of Cellular and Molecular Biology (LCMB) would like to identify peptide analogs of a natural wnt ligand by using the recombinant receptor to pan phage display peptide libraries. To this end, the NCI LCMB would like to establish a CRADA with a biotechnology company possessing phage display peptide libraries and interested in participating in the screening effort. Analogs identified in this manner would be tested for agonist or antagonist activity, and might serve as prototypes of reagents capable of modulating wnt signaling associated receptor pathways.

The role of the National Cancer Institute in this CRADA will include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience to the research project.

2. Planning research studies and interpreting research results.

3. Publishing research results.

The role of the CRADA Collaborator may include, but not be limited to:

1. Possession of a phage display peptide library.

2. Planning research studies and interpreting research results.

3. Providing support for onging CRADA-related research in the development of the particular application of the Technology.

(a) Financial support to facilitate scientific goals;

(b) Technical or financial support for further design of applications.