addresses the use of resistance testing in clinical phases of drug development and recommends the type of information that should be collected and the types of analyses that should be conducted to characterize an antiretroviral's resistance profile. This guidance also is intended to serve as a focus for continued discussions among the Division of Antiviral Products, pharmaceutical sponsors, the academic community, and the public.

This guidance is based on a 2-day session of the Antiviral Drug Product Advisory Committee convened on November 2 and 3, 1999, to address issues relating to HIV resistance testing, the division's experience with reviewing resistance data for antiretroviral drugs, and input from pharmaceutical sponsors and the HIV community.

This guidance has been updated to address public comments on the draft version. The following significant changes were made to the guidance: (1) The inclusion of more details and clarification on the recommendations about the amount and type of nonclinical studies that should be conducted before phase 1 clinical studies, (2) the inclusion of more details and clarification regarding data collection and types of analyses for treatment-naïve and treatment-experienced patients, (3) the inclusion of additional details regarding exposure-response analyses, and (4) updated guidance for submitting HIV resistance data.

The guidance reviews the role of resistance testing in initial activity and dose-finding studies, for study enrollment criteria, and background regimen selection. The guidance also reviews the use of resistance data to establish an indication. This guidance includes an appendix that provides recommendations on how to submit HIV resistance data to FDA.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the role of HIV resistance testing in antiretroviral drug development. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: October 24, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21403 Filed 10–30–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0049 (formerly Docket No. 02D–0049)]

Draft Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document for the public, FDA advisory committee members, and FDA staff entitled ''Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers.'' This guidance is intended to help the public, FDA advisory committee members, and FDA staff to understand and implement FDA procedures regarding public availability of information regarding certain financial interests and waivers granted by FDA to permit individuals to participate in an advisory committee meeting. The draft guidance announced in this notice supersedes FDA's ''Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees,'' dated January 2002.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by December 31, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Policy (HF–11), Office of the Commissioner, 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 telephone requests to 800–835–4709 or 301–827–1800.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jill Hartzler Warner, Office of Policy and Planning (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3370.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers,'' dated October 2007. FDA's advisory committees provide independent and expert advice on scientific, technical, and policy matters related to the development and evaluation of products regulated by FDA. FDA implements a rigorous process for soliciting and vetting candidates for advisory committee meetings to minimize any potential for financial conflicts of interest. The agency is authorized by statute to grant waivers to allow individuals with potentially conflicting financial

interests to participate in meetings where we conclude, after close scrutiny, that certain criteria are met. (See 18 U.S.C. 208(b)(1) and (b)(3) and section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (added by the Food and Drug Administration Amendments Act of 2007 (Public Law No. 110–85), section 701 (effective October 1, 2007).)

In the **Federal Register** of January 12, 2002 (67 FR 6545), FDA issued ''Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees,'' and requested comments on the draft guidance (Docket No. 02D–0049). The draft guidance was limited in application to special government employees (SGEs) participating in advisory committee meetings at which particular matters relating to particular products were discussed.

FDA has recently undertaken an internal assessment of its advisory committee process. As a result of this review, and based on the comments submitted to the docket for the January 2002 draft guidance, FDA is revising this draft guidance to broaden its applicability, bring as much transparency as possible to FDA's waiver process, and increase the consistency and clarity of the process. The draft guidance proposes revised procedures, consistent with section 712(c)(3) of the act, to make publicly available relevant information regarding financial interests and waivers granted by the agency for SGEs and regular Government employees invited to participate in FDA advisory committee meetings.

The draft guidance also includes a template for disclosing to the public the disqualifying financial interests for which waivers are sought and a template for all waivers that FDA grants. The guidance further describes FDA's process for making these documents available on its Web site in advance of each advisory committee meeting.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on public availability of information regarding advisory committee members' financial interests and waivers granted by FDA to permit participation in advisory committee meetings. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 24, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–5408 Filed 10–29–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are 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. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Immunostimulatory Combinations of TLR Ligands and Methods of Use

Description of Technology: New drugs or therapies that act by stimulating the immune system, or alternatively inhibiting certain aspects of the immune system, may be useful for treating various diseases or disorders, for example viral diseases, neoplasias, and/or allergies, and may also have use as vaccine adjuvants. However, although adjuvants have been suggested for use in vaccine compositions, there is an unmet need for adjuvants that can effectively enhance immune response.

Development of innate and adaptive immunity critically depends on the engagement of pattern recognition receptors (PRRs), which specifically detect microbial components named pathogen- or microbe-associated molecular patterns (PAMPs or MAMPs) (1–4). Toll-like receptors (TLRs) represent an important group of PRRs that can sense PAMPs or MAMPs once in the body. TLRs are widely expressed by many types of cells, for example cells in the blood, spleen, lung, muscle and intestines.

The present invention claims immunostimulatory combinations of TLR ligands and therapeutic and/or prophylactic methods that include administering an immunostimulatory combination to a subject. In general, the immunostimulatory combinations can provide an increased immune response compared to other immunostimulatory combinations and/or compositions. More specifically, combinations of TLR 2, 3 and 9 are claimed. The application also describes a novel mechanism for TLR synergy in terms of both signaling pathways and cytokine combinations.

Application: Development of improved adjuvants and/or synergistic combinations of adjuvants for vaccines.

Developmental Status: Compositions have been synthesized and preclinical studies have been performed.

Inventors: Jay Berzofsky and Qing Zhu (NCI).

Patent Status: U.S. Provisional Application filed 24 Sep 2007 (HHS Reference No. E–298–2007/0–US–01).

Licensing Status: Available for exclusive or nonexclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute's Vaccine Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this invention of synergistic combinations of TLR ligands. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.