Dated: December 10, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–3089]

Affirmative Agenda for International Activities—Center for Food Safety and Applied Nutrition, Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the Center for Food Safety and Applied Nutrition's (CFSAN) Affirmative Agenda for International Activities (International Affirmative Agenda). CFSAN intends to use the general framework of 2000 to 2002 priorities identified in the International Affirmative Agenda during its annual planning process to develop specific international activities for each of the 3 years.

ADDRESSES: The International Affirmative Agenda is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.1601, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John W. Jones, Office of Constituent Operations, Center for Food Safety and Applied Nutrition (HFS–550), 200 C St. SW., Washington, DC 20204, 202–205–4311.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 17, 1999 (64 FR 50518), FDA announced the availability of CFSAN's Draft International Affirmative Agenda for 2000 to 2002. FDA also solicited comments on whether to hold a public meeting on the Draft International Affirmative Agenda. Interested persons were given until October 1, 1999, to request a public meeting and until November 1, 1999, to comment. The current notice summarizes the comments received on the draft document and announces the availability of the final version of CFSAN's International Affirmative Agenda. CFSAN intends to use the general framework of 2000 to 2002 priorities identified in the International Affirmative Agenda during the center's annual planning process to develop specific international activities. CFSAN also intends to solicit public input on these planned international activities on an annual basis. Therefore, there will be continuing opportunity for public comment on CFSAN's planned international activities and on the center's overall international priorities.

II. Summary of Comments

FDA received eight letters, each containing one or more comments, on CFSAN's Draft International Affirmative Agenda from a consumer group, a food and drug professional association, and six industry trade associations. FDA received only one request for a public meeting and, based on this, the agency determined that there was not sufficient interest to conduct such a meeting. All of the substantive comments strongly supported the goals of CFSAN's Draft International Affirmative Agenda for 2000 to 2002. The comments articulated some concerns and made a number of suggestions.

A number of comments were related to FDA's public health mandate, the need for FDA to ensure that this mandate is not compromised by trade concerns, and the suggested need for FDA to promote proactively U.S. public health positions in deliberations of international standard setting bodies.

Most, but not all, of these comments suggested that CFSAN only participate in international activities that are consistent with and directly responsive to FDA's mission to protect the public health that is mandated explicitly by statute. Concern was expressed about possible CFSAN activities that appear to promote a particular technology (e.g., biotechnology) or that pertain to equivalence or mutual recognition agreements where, it was asserted, FDA's ability to protect public health would be lowered. There was also concern about any CFSAN activity related to the World Trade Organization (WTO) or North American Free Trade Agreement (NAFTA) that is undertaken explicitly to promote international trade at the expense of public health. The suggestion also was made that CFSAN should oppose actively the establishment of any standard by the Codex Alimentarius Commission (Codex) that does not provide a level of consumer protection equivalent to that which is provided by FDA regulation. One comment, however, suggested that FDA should undertake international activities specifically to support U.S. economic, trade, and market development interests overseas.

Some comments recommended that CFSAN strengthen its participation in Codex to ensure that Codex standards are based on sound scientific principles. These comments emphasized that CFSAN should work closely with the appropriate food industry representatives to develop technically accurate U.S. positions on matters before Codex and to ensure that Codex standards are practicable. The comments also suggested that CFSAN's participation in the Codex development process should be an agency priority and its delegates should be appropriately trained to strengthen the agency's participation.

Likewise, comments suggested that CFSAN take a more proactive and leadership role in developing appropriate work plans for the technical working groups (TWG's) convened under the NAFTA Sanitary and Phytosanitary (SPS) committee, particularly in the area of harmonized regulation procedures for food additives, safety assessments for foods derived from biotechnology, product recall and traceback procedures, and harmonized NAFTA positions on issues before Codex. The agency also was encouraged to be more actively involved in articulating the strength of the U.S. food regulatory system within the WTO's SPS committee.

FDA intends that all of CFSAN's international activities have as their basis maintenance and enhancement of U.S. public health. The draft International Affirmative Agenda states that consistency with FDA's primary public health mission is the first guiding principle of CFSAN's participation in any international activity. In this regard, CFSAN intends to participate in international activities that are intended, directly or indirectly, to enhance the safety, nutritional quality and informative and truthful labeling of foods, and the safety and labeling of cosmetics available to the American consumer, whether the products are produced in or imported into the United States. CFSAN also intends to participate, when practicable, in activities that address other compelling international or domestic public health issues, concerns or priorities identified by the Department of Health and Human Services and other domestic and foreign public health agencies that are important to CFSAN's areas of expertise and authority.

FDA emphasizes that CFSAN's international activities, including participation in committees of the Codex and other standard setting bodies, are aimed primarily at enhancing the agency's ability to protect

U.S. public health. In all international areas where standards are developed or decisions are made that bear on the safety and quality of foods and cosmetics that are produced in or imported into the United States, CFSAN intends to exercise leadership, authority, and influence to ensure that American consumers are protected by such standards and decisions. With regard specifically to bilateral agreements, FDA intends to enhance its ability to ensure that foods and cosmetics imported into the United States are safe through development of formal agreements with foreign governments, such as equivalence agreements, mutual recognition agreements, and memoranda of understanding, that are intended to provide FDA with reasonable assurance that products covered by such agreements consistently meet the U.S. level of public health protection.

CFSAN does not intend to undertake trade-related activities that are intended solely to promote U.S. trade interests or that have the effect of diminishing U.S. public health protection. CFSAN believes that it is appropriate, however, for the center to participate, where practicable, in international activities conducted in response to U.S. obligations under international treaties, trade agreements and other recognized, formal or informal arrangements of the United States. These activities include situations where CFSAN's participation is critical to help the United States resolve international trade disputes or preclude trade interruptions associated with foods and cosmetics for which FDA is the recognized competent U.S. authority.

Other comments were more specific in nature and related to the particular interests of the commenting organization. One comment generally supported CFSAN's proposed international priorities and indicated that the proposed activities, if implemented fully, would enhance FDA's ability to protect public health. The comment stated that the particular organization, which represents Federal, State, and local food and drug officials in the United States and Canada, is well positioned to work cooperatively with FDA and CFSAN, specifically, to implement CFSAN's international activities. In particular, the organization stated that a number of States represented by the association are willing to work collaboratively with FDA through Federal-State partnership agreements which, among other activities, might monitor imported foods to determine compliance with U.S. requirements, assist with trace backs of outbreaks of foodborne illnesses to their source, and improve compliance of imported foods with U.S. labeling requirements. The comment encouraged FDA to pursue additional partnerships with the states to help accomplish the regulatory and enforcement components of the CFSAN's international priorities and to work with the association to facilitate development of such partnerships.

FDA recognizes the continuing importance and advantages of working with state and local authorities on critical food and cosmetic issues, both domestic and international. The agency intends to work collaboratively with state and local regulatory officials through formal Federal-State partnerships and other approaches to leverage expertise and resources. The agency appreciates the organization's willingness to facilitate such collaboration with regard to imported foods and will consider means of enhancing cooperative activities in this area.

Additional comments stressed the importance of FDA finalizing its criteria for determining the equivalence of foreign food regulatory systems so that the United States can deal effectively and efficiently with diverse foreign regulatory systems. The agency was encouraged, for example, to conclude an equivalence agreement with Canadian authorities regarding fish and fishery inspection systems.

FDA intends to finalize its equivalence criteria for foods as soon as possible and to use the final criteria in future equivalence evaluations of foreign food safety regulatory systems.

Two comments strongly supported continuation of cosmetic industry trade association involvement in issuance of export certificates. The comments encouraged FDA to continue to permit cosmetic trade associations to issue export certificates on behalf of members, citing the time efficiency of the industry's program relative to that of any corresponding government certificate issuance activity. Conversely, another comment expressed the view that equivalence agreements, memoranda of understanding, and mutual recognition agreements should be developed between FDA and its trading partners as a means of reducing the need for export certificates.

FDA is currently examining the issue of the agency's involvement in issuance of export certificates for U.S.-produced foods and cosmetics.FDA also intends to finalize its equivalence criteria for foods as soon as possible. The agency will consider the associations' comments during its consideration of the agency's role in issuance of export certificates and whether any future equivalence agreements might reduce foreign requirements for such certificates.

One comment strongly encouraged CFSAN to participate in all relevant international discussions concerning development of harmonized international standards for cosmetics, particularly those discussions bearing on cosmetic trade among the United States, Canada, the European Union, and Japan. Other comments supported CFSAN's continuing involvement in development of mutual recognition agreements pertaining to cosmetics and provision of technical assistance to U.S. trade agencies to prevent or resolve trade disputes involving cosmetics. The comments also supported CFSAN's proposed priority to seek alternatives to animal testing for cosmetics.

CFSAN intends to participate, within resource constraints, in relevant international discussions concerning the safety and labeling of cosmetics to work to harmonize scientific and regulatory approaches, where such harmonization is practicable and maintains or enhances U.S. public health protection.

Two of the food trade associations commented that FDA should strengthen its participation in TWG's convened under NAFTA Sanitary and SPS committee in order to take a more proactive role in developing appropriate work plans for these groups. Specifically, one comment suggested that the TWG's could facilitate issues pertaining to harmonized registration procedures for food additives, safety assessments for foods derived from biotechnology, product recall and trace back procedures, and harmonized NAFTA positions on issues before Codex. This comment noted that FDA had not utilized the TWGs fully and encouraged CFSAN to undertake a greater leadership role in the TWGs. Two of the associations also encouraged FDA to become more actively involved in issues before the WTO's SPS committee, particularly with regard to articulating the strengths of the U.S. food regulatory system.

FDA agrees that the NAFTA TWG's provide an appropriate forum to address food safety, quality and labeling issues that are of interest to Canada, Mexico, and the United States. The agency also agrees that these TWG's can have a positive impact on public health protection and facilitation of the trade of safe food products among the three countries. CFSAN intends to strengthen its participation and leadership in these NAFTA TWG's to the extent practicable. CFSAN also intends to continue its participation in the WTO SPS

committee in order to promote and enhance public health protection in this forum.

Other comments by the food trade associations related to FDA and CFSAN resources needed to accomplish the proposed international priorities, the need for CFSAN to develop a more detailed list of specific activities within each of the broad priority areas in the draft International Affirmative Agenda, and a suggestion that CFSAN's ''first'' priority, both in its domestic and international activities, should be development, maintenance, and dissemination of its science base. Finally, several comments stressed that CFSAN should strive to involve the public fully in its international activities through appropriate notice and comment opportunities and other means.

III. Final CFSAN International Affirmative Agenda for 2000 to 2002

FDA appreciates the comments submitted by the eight organizations and recognizes that all of the comments have merit with regard to CFSAN's current and future international activities. The agency agrees, in principle, with most of the comments and believes that the priorities that CFSAN has articulated in its draft International Affirmative Agenda are compatible with all of the comments.

The international priorities as expressed in the International Affirmative Agenda represent a general framework for the center's international activities for 2000 to 2002. Many specific activities within the broader priority areas are to be planned and accomplished by the center on an annual basis over the next 3 years. Therefore, as these specific, annual international activities are identified and developed, CFSAN will solicit and consider additional public comments, in addition to those submitted on the draft International Affirmative Agenda.

Based on CFSAN's intent to consider comments on its specific international activities on an annual basis during development of its annual international program priorities, the center has elected to finalize CFSAN's International Affirmative Agenda without any changes from the original draft text.

Dated: December 10, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0483]

Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2.'' The guidance document addresses general and specific concerns for gene based detection techniques for human immunodeficiency virus (HIV). The document provides guidance on manufacturing and clinical trial design issues pertaining to the validation of tests based on nucleic acid detection either in the presence or absence of an amplification step.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2.'' The guidance document announced in this notice finalizes the draft guidance entitled ''Guidance for Industry in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Virus Type 1'' published in the **Federal Register** of July 10, 1998 (63 FR 37402). The guidance document clarifies the following issues as a result of public comments submitted on the draft guidance document: (1) The definition of limit of detection and limit of quantitation for a nucleic acid test and laboratory studies recommended for validation of these limits; (2) the analytical sensitivity study recommendations, including the FDA standard for sensitivity of the pool test in the case of nucleic acid testing, for testing pooled plasma; (3) the numbers of sites, specimens, and design of clinical specificity and sensitivity studies recommended for pooled plasma tests; and (4) the clinical studies to validate a claim for viral load tests used in patient management, i.e., prognosis and therapy.

The guidance document outlines some of the major regulatory and scientific issues concerning gene based tests for HIV–1 and HIV–2. These considerations also apply to tests for other transfusion transmitted viruses including hepatitis C virus, hepatitis B virus, and human T-cell Lymphotropic viruses types I and II.

The guidance document represents the agency's current thinking with regard to the manufacture and clinical evaluation of in vitro testing to detect specific nucleic acid sequences of HIV types 1 and 2. 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 statute, regulations, or both. As with other guidance documents, FDA does not intend this guidance to be all-inclusive and cautions that not all information may be applicable to all situations. The guidance document is intended to