7:30 a.m. to 5 p.m., and Friday, December 11, 1998, 8 a.m. to 5:30 p.m.

Location: The public workshop will be held at the Jack Masur Auditorium, Bldg. 10, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Contact: Abdur Razzaque, Center for Biologics Evaluation and Research (HFM–530), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0675.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number) to Karen Blackburn, Tascon, Inc., 1803 Research Blvd., suite 305, Rockville, MD 20850, 301–315–9000, ext. 514, FAX 301–738–9786, or e-mail kblackburn@tascon.com.

On December 10, 1998, beginning at 7:30 a.m., registration will be held at the public workshop location on a space available basis. However, because space is limited, interested parties are encouraged to register early. There is no registration fee for the public workshop.

If you need special accommodations due to a disability, please contact Karen Blackburn at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The goals of the workshop include discussing the following: (1) Regulatory considerations in the clinical development process for tumor vaccines; (2) morphological, immunophenotypic,and functional characteristics of dendritic cells; (3) current methods for physicochemical and functional characterization of autologous and allogeneic whole cell tumor vaccines, tumor cell lysates, polyvalent tumor antigen preparations, antigen presenting cells and other cell-derived vaccines; (4) novel preclinical strategies and biological/immunological assessments in early clinical trials; and (5) issues regarding the detection and monitoring of tumor cell contamination in cellular vaccines. The information obtained from these discussions will assist FDA and the interested public in developing policies and standards for product and clinical development for tumor vaccines.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

Dated: October 21, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–28908 Filed 10–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 19, 1998, 8 a.m. to 6:30 p.m., and on November 20, 1998, 8 a.m. to 3:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Persons: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 19, 1998, the committee will discuss issues relating to the use of cell substrates. On November 20, 1998, the committee will discuss issues relating to the manufacture and safety of live attenuated influenza virus vaccines.

Procedure: On November 19, 1998, from 8 a.m. to 1:30 p.m., and on November 20, 1998, from 8 a.m. to 3:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact persons by November 12, 1998. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:30 a.m. on November 19, 1998, and between approximately 8:15 a.m. and 8:30 a.m., and between approximately 10:20 a.m. and 10:50 a.m. on November 20, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 12, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On November 19, 1998, from 1:30 p.m. to 6:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). These portions of the meeting will be closed to discuss issues relating to pending or proposed investigational new drug applications.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 22, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–28904 Filed 10–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0451]

Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guide entitled ''Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables'' (the guide). The guide is designed to provide voluntary guidance on good agricultural practices and good management practices and to minimize microbial food safety hazards common to the growing, harvesting, packing, and transport of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (i.e., raw) form. This action is in response to the Presidential initiative to ensure the safety of imported and domestic fresh

fruits and vegetables. The voluntary guide is intended to assist growers, packers, and other operators in continuing to improve the safety of domestic and imported fresh produce.

ADDRESSES: Submit written requests for single copies of the guide to Lou Carson, Center for Food Safety and Applied Nutrition (HFS–32), 200 C St. SW., Washington, DC 20204, 202–260–8920. Send one self-addressed, self-adhesive label to assist that office in processing your request. Requests for copies of the guide should be identified with the docket number found in brackets in the heading of this document. A copy of the guide is available for public examination in the Dockets Management Branch, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. The guide is also accessible via the FDA home page on the World Wide Web (WWW) (http://www.fda.gov).

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–32), 200 C St. SW., Washington, DC 20204, 202–205–5916, FAX 202–260–9653, e-mail: ''jsaltsma@bangate.fda.gov'', or Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–2975, FAX 202–205–4422, e-mail: ''msmith1@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION: On October 2, 1997, the President announced the ''Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables'' (fresh produce safety initiative). As part of the fresh produce safety initiative, the President directed the Secretary of the Department of Health and Human Services (DHHS) and the Secretary of the U.S. Department of Agriculture (USDA), in cooperation with the agricultural community, to issue within 1 year guidance on good agricultural practices and good manufacturing practices for fresh fruits and vegetables. FDA is coordinating the effort for DHHS.

Between November 17, 1997, and December 12, 1997, FDA and USDA held a series of public meetings to provide the details on a broad approach on how to minimize microbial contamination of produce through the control of water, manure, worker health and hygiene, field and facility sanitation, and transportation. A draft guidance document entitled ''Working Draft: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables'' was made available electronically on FDA's home page on the WWW (http://www.fda.gov) and at each public meeting.

In the **Federal Register** notice of April 13, 1998 (63 FR 18029), FDA announced the availability of a proposed guidance document entitled ''Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.'' The proposed guidance document was also made available on FDA's home page and by mail to interested persons. The proposed guidance document responded to comments received on the working draft of the guidance document, as well as to comments received at the public meetings. FDA, in cooperation with USDA, held three public meetings between May 19, 1997, and May 27, 1998, to provide an overview of, and to seek additional public input on, the proposed guidance document. Transcripts of these meetings and all comments received on the proposed guide are on file in the Dockets Management Branch (address above) under the docket number appearing above and are accessible via the FDA home page on the WWW (http://www.fda.gov/ohrms/dockets).

In the April 13, 1998, notice, the agency asked for comments on the proposed guide and requested information about current agricultural practices, the cost of applying good agricultural and management practices, and ways to analyze costs and benefits to assess cost effective measures (63 FR 18029 at 18030). In response to that request, FDA received about 40 letters containing one or more comments in addition to many oral comments at the three public meetings held in May 1998. FDA has reviewed all of these comments, both oral and written, and has modified the proposed guide, as appropriate, in light of those comments. A number of comments were beyond the specific content of the guide. Therefore, the agency has prepared a written analysis of those comments, including those that addressed the agency's request for information about costs/benefits of agricultural practices, and has placed it in the docket (Docket No. 97N–0451). This analysis is available for review at the Dockets Management Branch (address above) or may be obtained via FDA's home page on the WWW (http://www.fda.gov/ohrms/dockets) under the docket number.

FDA is announcing the availability of the final guide. The guide responds to comments received on the proposed guidance document and represents FDA's and USDA's current thinking on strategies to minimize microbial hazards for fresh produce. The guide does not create or confer any rights for or on any person and does not operate to bind FDA, USDA, or the public. The guide is being distributed in accordance with the FDA's policy for Level 1 guidance documents as set out in the agency's Good Guidance Practices, published in the **Federal Register** of February 27, 1997 (62 FR 8961).

FDA believes that this guidance serves as an important step in addressing the risks of foodborne illness associated with fresh produce. There are, at this time, limited data available on current agricultural practices. To gather better data and provide a foundation for the agency's future evaluation of the impact of the guidance, FDA is working with USDA's National Agricultural Statistics Service (NASS) to design and conduct a survey of current domestic agricultural production and packing practices for fresh produce. The objective of the survey is to document the prevalence and variety of practices currently used in the production of fresh fruits and vegetables in the United States. The survey will focus on practices that are addressed in the guide, including practices related to agricultural water quality, manure management, packinghouse sanitation, and worker hygiene. The survey development process has included an industry advisory group to help ensure the effectiveness of the survey. NASS plans to conduct a pilot test survey of two States and approximately 30 commodities in fiscal year (FY) 1999 and, depending on resources, to conduct a nationwide survey in FY 2000.

Dated: October 26, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29022 Filed 10–26–98; 2:39 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0217]

Proposals to Increase the Legal Availability of Animal Drugs for Minor Species and Minor Uses; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled ''Proposals to Increase the Legal Availability of Animal Drugs for Minor