

Advisor, ATSDR, M/S E-28, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639-0730, FAX 404/639-0759.

Dated: June 18, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96-15974 Filed 6-21-96; 8:45 am]

BILLING CODE 4163-70-M

Administration for Children and Families, Office of Child Support Enforcement

Statement of Organization, Functions, and Delegations of Authority

This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (DHHS), Administration for Children and Families (ACF) as follows: Chapter KF, The Office of Child Support Enforcement (OCSE) (60 FR 39961), as last amended, August 4, 1995. This restructuring will establish a new division within the OCSE.

1. Amend KF.10 Organization. Delete in its entirety, and replace it with the following:

KF.10 Organization. The Office of Child Support Enforcement is headed by a Director and consists of: Office of the Director (KFA) Division of Audit (KFB) Division of Program Operations (KFC) Division of Policy and Planning (KFD) Division of Consumer Services (KFE) Division of State and Local Assistance (KFF)

2. Amend KF.20 Functions.

a. Delete first paragraph of paragraph A, and replace it with the following:

KF.20 Functions. A. Office of the Director. The Director is also the Assistant Secretary for Children and Families and is directly responsible to the Secretary for carrying out OCSE's mission. The Deputy Director has day-to-day operational responsibility for Child Support Enforcement programs. The Associate Deputy Director for Information Systems, who is also the Director of the ACF Office of Regional Operations and State Systems, has responsibility for day-to-day management of child support information systems. The Deputy Director assists the Director in carrying out responsibilities of the Office and oversees day-to-day operation of OCSE's Audit, Program Operations, Policy and Planning, Consumer Services and State and Local Assistance Divisions. The Associate Deputy Director assists the

Deputy Director in carrying out the responsibilities of the Office.

b. Delete paragraph C in its entirety, and replace it with the following:

C. Division of Program Operations monitors implementation of program requirements and coordinates child support enforcement activities with regional offices. The Division provides specialized services and operation of the Federal Parent Locator Service, the Federal Tax Refund Offset Program, Project 1099, the IRS Full Collection Project and the Parental Kidnapping Service. It monitors contracts with organizations affiliated with child support enforcement programs. The Division provides outreach and liaison services to a variety of special interest populations concerning establishment of paternity and collection of child support.

c. Add paragraph F. Add the following to establish paragraph F:

F. Division of State and Local Assistance in concert with OCSE regional offices, assesses State performance and provides information and assistance on Child Support Enforcement state operations. It provides national direction and leadership for training and technical assistance activities to increase Child Support Enforcement (CSE) program effectiveness both at Federal and State levels; develops guides and resource materials and serves as a clearinghouse for specialized program techniques for use by ACF regional offices and States; and ensures transfer of best practices among State and local CSE enforcement agencies. The Division develops and publishes informational materials and operates a national CSE training center; provides logistical support for both training events and meetings; and monitors contracts with organizations affiliated with child support enforcement programs in the areas of training and technical assistance.

Dated: June 17, 1996.

Mary Jo Bane,

Assistant Secretary for Children and Families.

[FR Doc. 96-15919 Filed 6-21-96; 8:45 am]

BILLING CODE 4184-01-M

Food and Drug Administration

[Docket No. 94F-0047]

Atlantis Corp., Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

withdrawal, without prejudice to a future filing, of a food additive petition (FAP 4A4409) proposing that the food additive regulations be amended to provide for the safe use of shark liver oil as a dietary supplement for humans.

FOR FURTHER INFORMATION CONTACT:

Lawrence J. Lin, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3103.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of March 24, 1994 (59 FR 13970), FDA announced that a food additive petition (FAP 4A4409) had been filed by Atlantis Corp., 15 Tommy's Lane, East Freetown, MA 02717. The petition proposed to amend the food additive regulations to provide for the safe use of shark liver oil as a dietary supplement for humans. Atlantis Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: June 10, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96-15992 Filed 6-21-96; 8:45 am]

BILLING CODE 4160-01-F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline

will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Transmissible Spongiform Encephalopathies Advisory Committee Meeting (formerly Ad Hoc Advisory Committee on Creutzfeldt-Jakob Disease)

Date, time, and place. July 2, 1996, 1 p.m., Woodmont I Bldg., conference room 200S, 1401 Rockville Pike, Rockville, MD.

Type of meeting and contact person. This meeting will be held by a telephone conference call. A speaker telephone will be provided in the conference room to allow public participation in the meeting. Open public hearing 1 p.m. to 2 p.m., unless public participation does not last that long; open committee discussion, 2 p.m. to 5 p.m.; Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3514, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Transmissible Spongiform Encephalopathies Advisory Committee, code 12388. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates available scientific data concerning the safety of products which may be at risk for transmission of spongiform encephalopathies having an impact on the public health.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before June 24, 1996, 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 required to make their comments.

Open committee discussion. The committee will review and discuss revised precautionary measures to reduce the possible risk of transmission of Creutzfeldt-Jakob Disease by blood and blood products. FDA regrets that it was unable to publish this notice 15 days prior to the July 2, 1996, Transmissible Spongiform Encephalopathies Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue

to public discussion and qualified members of the Transmissible Spongiform Encephalopathies Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

National Mammography Quality Assurance Advisory Committee

Date, time, and place. July 10, 11, and 12, 1996, 9 a.m., DoubleTree Hotel—Rockville, Main Ballroom, 1750 Rockville Pike, Rockville, MD. A limited number of overnight accommodations have been reserved at the DoubleTree Hotel—Rockville. Attendees requiring overnight accommodations may contact the hotel at 301-468-1100 and reference the FDA committee meeting block, group code 0301. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open public hearing, July 10, 1996, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; open committee discussion, July 11, 1996, 9 a.m. to 5 p.m.; open subcommittee discussions, July 12, 1996, 9 a.m. to 1 p.m.; open committee discussion, 1 p.m. to 5 p.m.; Charles K. Showalter, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), National Mammography Quality Assurance Advisory Committee, code 12397. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee advises on developing appropriate quality standards and regulations for the use of mammography facilities.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before July 5, 1996, 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 required to make their comments.

Open committee discussion. On July 10, 1996, the committee will hear updates on approvals for alternative

standards under the Mammography Quality Standards Act (MQSA) of 1992. On July 10 and 11, 1996, the committee will discuss digital mammography under the MQSA. On July 12, 1996, the committee will discuss the issue of States as certifying bodies under the MQSA as well as the ongoing work of the three subcommittees: Access to Mammography Services, Physicists Availability, and Cost Benefit of Compliance.

Open subcommittee discussions. On July 12, 1996, the three subcommittees will meet concurrently. The subcommittees will discuss information which is necessary to make the determinations and subsequently prepare the reports as mandated in the MQSA. Upon completion, the subcommittee reports will be reviewed by the committee prior to submission to the Secretary and Congress.

Medical Imaging Drugs Advisory Committee

Date, time, and place. July 22, 1996, 8:30 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, July 22, 1996, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 2:30 p.m.; open public hearing, 2:30 p.m. to 3 p.m.; William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM-21), Food and Drug Administration, 1401 Rockville Pike, Bethesda, MD 20852, 301-827-0314, or Leander Madoo, Center for Drug Evaluation and Research (HFD-21), 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Medical Imaging Drugs Advisory Committee, code 12540. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before July 15, 1996, and

submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of the proposed participants, and the indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss the Center for Biologics Evaluation and Research's product license application 95-0041 for Prostascint™ (Cytogen Corp.), a radiolabeled monoclonal antibody designed to detect sites of metastatic cancer which express the prostate specific membrane antigen.

Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. July 22 and 23, 1996, 8:30 a.m., Gaithersburg Marriott Washingtonian Center, Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD; July 24, 1996, 8:30 a.m., Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Marriott Washingtonian Center. Attendees requiring overnight accommodations may contact the hotel at 301-590-0044 and reference the FDA panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Shirley Meeks, Conference Management, 301-594-1283, ext. 113. The availability of appropriate accommodations cannot be ensured unless prior notification is received.

Type of meeting and contact person. Open committee discussion, July 22, 1996, 8:30 a.m. to 2 p.m.; open public hearing, 2 p.m. to 3 p.m., unless public participation does not last that long; open committee discussion, 3 p.m. to 7 p.m.; open committee discussion, July 23, 1996, 8:30 a.m. to 11 a.m.; open public hearing, 11 a.m. to 11:30 a.m., unless public participation does not last that long; open committee discussion, 11:30 a.m. to 3 p.m.; open public hearing, 3 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 7 p.m.; open committee discussion, July 24, 1996, 8:30 a.m. to 12 m.; Alfred W. Montgomery, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Obstetrics and Gynecology Devices

Panel, code 12524. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before July 12, 1996, 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 required to make their comments.

Open committee discussion. On July 22, 1996, the committee will be asked to consider new technological advances in intrapartum electronic fetal monitoring (EFM). After hearing a series of presentations on the subject, the committee will discuss appropriate recommended testing for such new technology applications. FDA will consider these recommendations in the future development of testing guidelines. Committee deliberations on this subject will continue to the second day, July 23, 1996. FDA recognizes that there continues to be questions asked about EFM and its place in the clinical management of the patient in labor. The intent of the committee discussion is not to resolve issues related to clinical practice and clinical standards in the area of EFM. Rather, the focus of discussions will be on reasonable study methodologies for establishing the safety and effectiveness of the new fetal monitoring technologies.

On July 23, 1996, following the discussions on new technological advances in intrapartum EFM, the committee will discuss and vote on a premarket approval application (PMA) for an implantable stent used for in utero treatment of fetal postvesicular uropathy. Also, on July 23, 1996, following deliberations on the above PMA, the committee will discuss and vote on a PMA for a silicone barrier contraceptive device. On July 24, 1996, the committee will continue deliberations on the contraceptive device PMA.

Anti-Infective Drugs Advisory Committee

Date, time, and place. July 24, 25, and 26, 1996, 8:30 a.m., Holiday Inn—Silver

Spring, Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open public hearing, July 24, 1996, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; open committee discussion, July 25, 1996, 8:30 a.m. to 5 p.m.; open public hearing, July 26, 1996, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 2 p.m.; Ermona B. McGoodwin or Danyiel D'Antonio, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Anti-Infective Drugs Advisory Committee, code 12530. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before July 19, 1996, 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 required to make their comments.

Open committee discussion. On July 24, 1996, the committee will discuss issues relevant to: (1) The use of silver sulfadiazine cream 1% in the treatment of patients with chronic wounds; and (2) new drug application (NDA) 19-832, Sulfamylon® Solution 5% (mafénide acetate, Mylan Pharmaceuticals, Inc.) for the control of bacterial colonization under moist dressings over meshed autografts on excised burn wounds. On July 25 and 26, 1996, the committee will discuss antibiotic resistance issues. In light of the significant public health impact of increasing bacterial resistance on the future usefulness of antimicrobial agents, FDA is soliciting from the advisory committee opinions and advice regarding the development of policy for antimicrobial drugs intended for the treatment of multidrug resistant (MDR) organisms. Issues for discussion include labeling for the treatment of MDR organism(s), and labeling as second line

therapy versus empiric therapy since widespread empiric use may decrease the drug's potential usefulness for treating MDR organisms. The agency encourages investigators, academicians, and members of the pharmaceutical industry with information relevant to the treatment of infections caused by MDR organisms, including current approaches to antimicrobial drug development, to respond to this notice.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to

make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: June 14, 1996.
Michael A. Friedman,
Deputy Commissioner for Operations.
[FR Doc. 96-15942 Filed 6-21-96; 8:45 am]
BILLING CODE 4160-01-F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

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This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Psychopharmacologic Drugs Advisory Committee

Date, time, and place. July 15, 1996, 8:30 a.m., Holiday Inn—Silver Spring, Main Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Kennerly Chapman, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 1901 Chapman Ave., rm. 200, Rockville, MD 20852, 301-443-5455, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Psychopharmacologic Drugs Advisory Committee, code 12544. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of psychiatry and related fields.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations must notify the contact person before July 10, 1996, 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 required to make their comments.

Open committee discussion. The committee will discuss the safety and effectiveness of Serlect® (sertindole), new drug application (NDA) 20-644, Abbott Laboratories, for use in the treatment of psychotic disorders.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee