



Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

ANNUAL REPORT
OF THE
ALLERGENIC PRODUCTS ADVISORY COMMITTEE
for the period
October 1, 1998 through September 30, 1999

FUNCTION

The Committee reviews and evaluates available data relating to the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention or treatment of allergies and allergic disease, and makes appropriate recommendations to the Commissioner of Food and Drugs of its findings regarding the affirmation or revocation of biological product licenses, on the safety, effectiveness, and labeling of the products, on clinical and laboratory studies of such products, on amendments or revisions to regulations governing the manufacture, testing, and licensing of allergenic biological products, and on the quality and relevance of FDA's research programs which provide the scientific support for regulating these agents.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met one time during the reporting period on February 22, 1999. The meeting was held in Bethesda, Maryland.

The meeting included a closed session to permit discussion of trade secret and confidential commercial information.

ACCOMPLISHMENTS

At the February 22, 1999 meeting:

1. In open session the committee reviewed and discussed organizational changes, regulatory activities, operational issues, and research activities of the Laboratory of Immunobiochemistry (LIB).
2. In open session the committee reviewed and discussed potency limits of standardized allergen vaccines, the measurement of protein content of allergen vaccines, the current status of Class IIIA allergen extracts, compliance issues, and the clinical activities of Division of Allergenic Products.
3. In closed session the committee discussed trade secret or confidential commercial information related to a clinical trial design of an IND (5 U.S.C. 552b(c)(4)).

November 1, 1999
Date

William Freas
William Freas, Ph.D.
Acting Executive Secretary

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CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

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Food and Drug Administration
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Rockville MD 20852-1448

ANNUAL REPORT
OF THE
BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE
for the period
October 1, 1998 though September 30, 1999

FUNCTION

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of biological response modifiers which are intended for use in the prevention and treatment of a broad spectrum of human diseases. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met three times during the reporting period including a meeting of the Xenotransplantation Subcommittee. Meetings were held in Bethesda, Maryland.

The dates of those meetings were: November 13, 1998; June 3-4, 1999; and July 15, 1999.

The meeting on July 15 included a closed session to permit discussion of matters of a personal nature.

ACCOMPLISHMENTS

At the November 13, 1998 meeting:

In open session, the Committee discussed general scientific issues related to allogeneic transplantation with a focus on haplo-identical transplantation and other high risk transplantation.

At the June 3-4, 1999 meeting:

In open session, the Xenotransplantation Subcommittee of the Biological Response Modifiers Advisory Committee discussed and made recommendations regarding scientific data concerning porcine endogenous retrovirus; patient monitoring and screening data concerning patients who have received a porcine xenograft; FDA's xenotransplantation policy development; and discussed proposals for solid organ xenotransplantation.

At the July 15, 1999 meeting:

In open session, the Committee discussed and made recommendations on the implications of fast track and the pediatric rule on biological product development; and immune reactions to therapeutic and diagnostic biological products. In addition, the Committee discussed the report of the June 3-4, 1999 meeting of the Xenotransplantation Subcommittee and were updated on the research programs of the Laboratory of Cytokine Research.

In closed session, the committee recommended personnel and program actions for the Laboratory of Cytokine Research, Division of Cytokine Biology. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

10-29-99
Date

Gail M. Dapolito
Gail M. Dapolito
Executive Secretary

BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION

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ANNUAL REPORT
OF THE
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
for the period
October 1, 1998 through September 30, 1999

FUNCTION

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met four times during the reporting period. Meetings were held in Bethesda, Maryland. One meeting was a teleconference.

The dates of those meetings were: November 19-20, 1998; January 29, 1999; March 11, 1999; and September 14-15, 1999.

The meetings on November 19-20, 1998 and September 14-15, 1999 included closed sessions to permit discussion of trade secret or confidential commercial information or matters of a personal nature.

ACCOMPLISHMENTS

At the November 19-20, 1998 meeting:

1. In open session, the committee was briefed on products approved since the last Vaccines meeting including Certiva, a DtaP vaccine, RotaShield, and a supplement for the reissuance of a license for a BCG vaccine.
2. In open session, the committee listened to presentations describing the need to address the possibility of expanding the types of tissue that can be used for vaccine production. In particular, CBER wanted guidance on use of neoplastic cell lines as vaccine substrates. The Committee commented on issues relating to the topic and charged FDA to move forward.
3. In open session, the committee provided guidance on matters with known or theoretical capability to affect the safety of live influenza virus vaccines. These matters required guidance before the approval and widespread use of live attenuated vaccines.
4. In closed session, the committee discussed important issues related to the interference between multiple vaccines. Several suggestions were offered for ways to communicate the matter to all populations, including physicians, for post-marketing surveillance, and on increased use of animal models to predict immune responses (5 U.S.C. 552b(c)(4)).
5. In closed session, the committee was updated on efficacy data from a large trial of heptavalent pneumococcal conjugate vaccine (5 U.S.C. 552b(c)(4)).
6. In closed session, the committee was briefed on FDA's "Refusal to File" for a Lyme disease vaccine and on steps taken since the May 1998 Vaccine meeting toward the licensure of a different Lyme disease vaccine (5 U.S.C. 552b(c)(4)).
7. In closed session, the committee received a briefing on a clinical trial initiated in November 1998 to study use of chickenpox vaccine for preventing herpes zoster, or shingles, in elderly individuals (5 U.S.C. 552b(c)(4)).
8. In closed session, the committee was made aware of FDA's "Refusal to File" action on a live attenuated influenza virus vaccine (5 U.S.C. 552b(c)(4)).

At the January 29, 1999 meeting:

1. In open session, the committee discussed the formulation of influenza virus vaccine for the 1999-2000 season. The committee recommended one of the strains to be included in the vaccine for the 1999-2000 season. Data were insufficient at that point for selections on the other strains to be included in the trivalent vaccine.

2. In open session, the committee heard updates on activities leading to the design and production of an H5 vaccine. These studies are pointing out important lessons for pandemic planning.

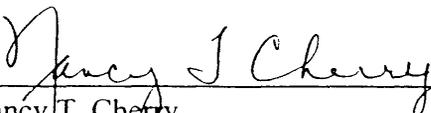
At the March 11, 1999 meeting:

1. In open session, the committee convened by teleconference to complete the process of strain selection begun at the previous meeting for the formulation of influenza virus vaccine. Recommendations were made on the H3 and B components of the vaccine. Members called for more studies on the efficacy and performance of influenza virus vaccine each year. They also called for a mechanism for increased studies in children and urged that aggressive action be taken to secure the necessary funding.

At the September 14-15, 1999 meeting:

1. In open session, the committee heard a report on the Thimerosal Workshop and on efforts to find ways to reduce and eliminate the mercury in vaccines.
2. In open session, the committee was briefed on the Cell Substrate Workshop. The workshop was designed to stimulate discussion of new and novel cell substrates.
3. In open session, the committee heard data on adverse events occurring in infants receiving the new vaccine for rotavirus, RotaShield.
4. In closed session, the committee was alerted to new vaccines in development for rotavirus (5 U.S.C. 552b(c)(4)).
5. In open session, the committee heard presentations by two CBER employees on their scientific activities.
6. In closed session, the committee reviewed the site visit report evaluating the laboratory activities of two CBER scientists. Disclosure of the information during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6).
7. In open session, the committee advised CBER on issues relating to the evaluation of meningococcal conjugate vaccines. Some meningococcal conjugate vaccines are now in clinical studies, and the committee's guidance will be useful to assess product efficacy for potential licensure.

November 2, 1999
Date



Nancy T. Cherry
Executive Secretary

**VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH**

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ANNUAL REPORT
OF THE
ANTIVIRAL DRUGS ADVISORY COMMITTEE
for the period
October 1, 1998 through September 30, 1999

FUNCTION

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 acquired immune deficiency syndrome (AIDS), HIV-related illnesses, and other viral, fungal, and mycobacterial infections, and makes appropriate recommendations to the Commissioner of Food and Drugs. The Committee also provides critical review of agency sponsored intramural and extramural research programs in support of the FDA's regulatory functions.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Committee met 6 times during the reporting period in Gaithersburg or Bethesda, Maryland. The meeting dates were October 6, 1998, November 2, 1998, December 1, 1998(joint with Nonprescription Drugs), February 24, 1999, July 27, 1999, and July 29, 1999.

The meeting on July 27, 1999 was a meeting of a subcommittee on Immunosuppressive Drugs.

The meeting on July 29, 1999 was a closed session to permit discussion of trade secret or confidential commercial information.

ACCOMPLISHMENTS

On October 6, 1998, the Committee discussed data relevant to an application submitted by Glaxo Wellcome, Incorporated to market lamivudine tablets and oral solution (Epivir-HBV™), for the treatment of chronic hepatitis B. The Committee recommended approval and the agency concurred, approving the application on December 8, 1998.

On November 2, 1998, the Committee discussed data relevant to an application submitted by Glaxo Wellcome, Incorporated to market abacavir tablets and oral solution (Ziagen™), for the treatment of HIV infection in adults and pediatric patients ≥ 3 months. The Committee recommended approval and the agency concurred, approving the application on December 18, 1998.

On December 1, 1998, the Committee (joint with Nonprescription Drugs) discussed data relevant to an application submitted by SmithKline Beecham to switch Denavir cream as indicated for the treatment of herpes labialis in immunocompetent adults from Prescription to Over-The-Counter status. The Committees did not recommend approval. To date, the agency has not granted Denavir OTC status.

On February 24, 1999, the Committee discussed data relevant to an application submitted by Glaxo Wellcome, Incorporated to market zanamavir for inhalation (Relenza®), for the treatment of influenza A and B. The Committee recommended approval and the agency concurred, approving the application on July 27, 1999.

On July 27, 1999, a Subcommittee on Immunosuppressive Drugs discussed data relevant to an application submitted by Wyeth Ayerst Laboratories to market sirolimus (Rapamune®) for the prophylaxis of organ rejection in patients receiving renal transplants. The subcommittee recommended approval and the agency concurred, approving the application on September 15, 1999

On July 29, 1999, the meeting was closed to permit the discussion of trade secret or confidential commercial information (5 U.S.C. 552b(c)(4)). An open session that consisted entirely of an open public hearing was scheduled for the first hour of the meeting. However, there were no open public hearing participants and the morning closed session commenced. In the afternoon, the Division of Antiviral Drug Products presented an Annual Update to the committee.

11/19/99
Date


Rhonda Stover, RPh
Executive Secretary

**ANTIVIRAL DRUGS ADVISORY COMMITTEE
CENTER FOR DRUG EVALUATION AND RESEARCH**

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ANNUAL REPORT

Of the

ARTHRITIS ADVISORY COMMITTEE

For the period

October 1, 1998 through September 30, 1999

FUNCTION

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

MEMBERSHIP

A roster of members is attached.

MEETINGS

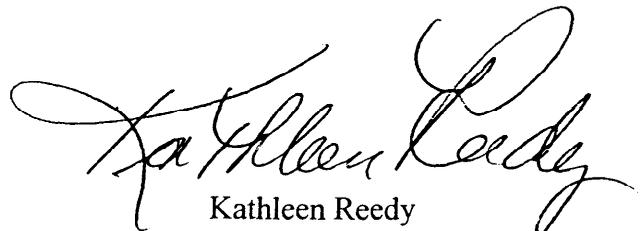
The committee met four times during the reporting period in Gaithersburg and Silver Spring, Maryland. The dates of these meetings were December 1 and 2, 1998, February 23, 1999, April 20 and 21, 1999 and July 20 and 21, 1999.

The meetings of December 2, 1998 and April 21, 1999 were closed sessions to permit discussion of trade secret or confidential commercial information. The Annual Update on December 2 included presentation of Investigational New Drugs and New Drug Applications in Phase I and II and any stage of Phase III to the Committee for their information. Center for Biologics Evaluation and Research presented products in the process of review for the indication of rheumatoid arthritis. The issue at the December 2, 1998 meeting was discussion of a phase 4 clinical trial design

ACCOMPLISHMENTS

See next page.

December 15, 1999



Kathleen Reedy
Executive Secretary

Arthritis Advisory Committee of FDA
Closed Meeting Report October 1, 1999 through September 30, 2000

At the December 1-2, 1998 meeting:

In open session, the Committee met to consider the safety and efficacy of NDA 20-998, Celebrex, (celecoxib) Searle, for the treatment of acute or chronic signs and symptoms of osteoarthritis and rheumatoid arthritis and the management of pain. The committee recommended the approval of the product for rheumatoid and osteoarthritis and the agency has approved the product.

In closed session on April 2, the committee met to hear an update on products under review.

At the February 23, 1999 meeting:

In open session, the Committee met to discuss issues of design and assessment of clinical trials of drugs, biologics, and devices that are being developed for treatment of systemic lupus erythematosus.

At the April 20-21, 1999 meeting:

In open session, the committee considered the safety and efficacy of NDA 21-042, Vioxx (rofecoxib), Merck, for the treatment of acute or chronic signs and symptoms of osteoarthritis and the management of pain. The committee recommended approval of the product and the agency has approved it.

In closed session on April 21, the committee met to discuss clinical trial design for a specific class of drugs.

At the July 20-21, 1999 meeting:

In open session, the committee met jointly with the Nonprescription Drugs Advisory Committee to discuss the issues of concern for New drug Application (NDA) 21-070 for Flexeril (cyclobenzaprine HCl) Merck, proposed for over the counter to treat muscle spasms.

In open session, the Committee discussed evidence needed to establish that a drug product has a beneficial effect on joint structure in patients with osteoarthritis.

**ARTHRITIS ADVISORY COMMITTEE
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ANNUAL REPORT
of the
DERMATOLOGIC AND OPHTHALMIC DRUGS ADVISORY COMMITTEE
for the period
October 1, 1998 through September 30, 1999

FUNCTION

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 dermatologic and ophthalmic disorders and make appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met three times during the reporting period in Rockville and Bethesda, Maryland. The dates of those meetings were:

October 21-22, 1998
October 23, 1998
July 21, 1999

The meeting on October 22, 1998, included a closed session to permit discussion of trade secret or confidential commercial information.

ACCOMPLISHMENTS

On October 21 and 22, 1998, the full committee conducted three general scientific discussion sessions regarding clinical trial design issues for products indicated for treatment of psoriasis, for biologic products indicated for treatment of psoriasis and for products indicated for treatment of tinea capitis. The committee, the guest experts, and the FDA review personnel discussed the current state of knowledge of the diseases and current treatment options. They then considered

what would be appropriate approaches to determining productive primary, co-primary, and secondary endpoints for conducting clinical trials of potential treatments, especially using currently accepted or proposed severity factors and measurement instruments. The meeting on October 22 included a closed session to permit discussion of trade secret data and/or confidential commercial information [5 U.S.C. 552b(c) (4)].

On October 23, 1998, the committee met in joint session with the Pharmaceutical Science AC to discuss issues relevant to the potential usefulness of dermatopharmacokinetic (DPK) methodology in determining bioequivalence of topical dermatological products. Although the dermatology and statistical members of the Committee stated that they had not been provided adequate information to make recommendations, they raised a number of potential benefits and drawbacks, as they had in the March 19, 1998, meeting which discussed the same topic. In accordance with new FDA governing legislation, a guidance document for determining BE will be written.

9 December 1999
Date


Theresa K. Riley
Executive Secretary

DERMATOLOGIC & OPHTHALMIC DRUGS ADVISORY COMMITTEE

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ANNUAL REPORT
of the
DRUG ABUSE ADVISORY COMMITTEE
for the period
October 1, 1998 through September 30, 1999

FUNCTION

The Committee advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice with regards to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by the Department of Health and Human Services with regard to the marketing, investigation, and control of such drugs or other substances.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met one time during the reporting period in Rockville, Maryland. The date of the meeting was April 20, 1999.

The meeting on April 20, 1999, included a closed session to permit discussion of trade secret or confidential commercial information.

ACCOMPLISHMENTS

On the morning of April 20, 1999, the Committee met in open session to discuss appropriate patient populations and outcome measures for clinical trials for drugs to treat alcohol use disorders.

On the afternoon of April 20, 1999, the Committee met in closed session to discuss trade secret and/or confidential commercial information related to product development (5 U.S.C. 552b(c)(4)).

9 December 1999
Date


Theresa K. Riley
Executive Secretary

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ANNUAL REPORT
of the
ONCOLOGIC DRUGS ADVISORY COMMITTEE
for the period
October 1, 1998 through September 30, 1999

FUNCTION

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Committee met five times during the reporting period in Gaithersburg, Bethesda and Silver Spring, Maryland. The dates of those meetings were November 16, 1998, January 12 and 13, 1999, March 23, 1999, June 7 and 8, 1999 and September 16 and 17, 1999. Part of the meeting on March 23, 1999 was held in closed session to permit the discussion of trade secret and/or confidential commercial information.

ACCOMPLISHMENTS

On November 16, 1998, the Committee met to consider NDA 20-886, Panretin® (alitretinoin) Gel 0.1%, from Ligand Pharmaceuticals Inc., indicated for the first-line topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma. The Committee advised removing the words "first-line" from the proposed indication, due to concerns that this topical treatment might be automatically chosen when a systemic therapy would be more appropriate. The Committee agreed with the Open Public Hearing speakers that the psychological and aesthetic considerations were important and felt that there is a niche for this drug when the patient is adverse to the cytotoxicity of a systemic

therapy, or in conjunction with systemic therapy, and recommended approval. A letter of approval was sent on February 5, 1999. The Committee also discussed data pertaining NDA 21-041 DepoCyt™ (DTC 101, liposomal cytarabine), from DepoTech Corporation, indicated for intrathecal therapy of lymphomatous meningitis. The Committee felt that there was uncertainty that DepoCyt showed a clear superiority in these trials, as missing data, the large number of variables and the small size of the trial preclude making comparative conclusions. However, there is no approved drug for this indication and DepoCyt does show activity by CSF cytologic response and has a relatively convenient and nondisruptive dosing schedule. The Committee voted for approval and a letter of approval was sent on April 5, 1999.

On January 12, 1999, the Committee evaluated the data concerning NDA 21-029 and NDA 21-050, Temodal® (temozolomide) Capsules, from Schering Corporation, indicated for the treatment of adult patients with malignant glioma (glioblastoma multiforme and anaplastic astrocytoma) at first relapse. The Committee had serious concerns about using a retrospectively chosen end-point (6-month progression-free survival) for the glioblastoma indication, when the data show no evidence of improvement in overall survival, and recommended unanimously against approval for that indication. For the indication for anaplastic astrocytoma, the Committee unanimously recommended accelerated approval. The drug was approved for the treatment of anaplastic astrocytoma on September 24, 1999. On January 13, the Committee reviewed NDA 50-766, Prograf® (tacrolimus), from Fujisawa Healthcare, Inc., indicated for the prophylaxis of graft-versus-host disease in patients receiving allogeneic bone marrow transplants. The Committee felt that a confirmatory trial would be necessary to further investigate safety and toxicity issues. It does appear that Prograf can be immunosuppressive and prevent graft-versus-host disease, but the safety concerns could limit its use to the least favorable clinical settings (unrelated donors, high risk patients. The vote was 9-4 against approval. Also on January 13, 1999, considered data relevant to NDA 20-765 OraTest™ (tolonium chloride), from Zila, Inc. OraTest™ is an oral rinse that is indicated for use as a diagnostic adjunct in patients with oral lesions suspected or known to be malignant, to help in detection of all sites of cancer, definition of borders or cancerous lesions, and selection of sites to be biopsied. The Committee indicated that the data was not of high enough quality to determine the true rate of false positive and false negative readings. They recommended unanimously against approval based on the data presented.

On March 23, 1999, the Committee met to consider NDA 21-051, Temodal® (temozolomide) Capsules, from Schering Corporation, indicated for the first line treatment of patients with advanced metastatic malignant melanoma. The Committee felt that the trial results failed to show superiority of temozolamide over dacarbazine in either overall survival or progression-free survival, and voted against recommending approval. Also on March 23, 1999, the Committee met in closed session for the discussion of trade secret and/or confidential commercial information related to product development (5U.S.C. 552b (c)(4)).

On June 7, 1999, the Committee heard presentations regarding the use of time to tumor progression (TTP) as a possible basis for marketing approval of cytotoxic drugs for initial treatment of advanced metastatic breast cancer. The Committee felt that TTP is not a sufficiently reliable surrogate to be the basis of unqualified regular approval, but that TTP could be a sufficiently reliable surrogate for accelerated approval with confirmation of effect on survival or other patient benefit needed in Phase 4 to qualify for regular approval. The demonstration of a clinically realistic survival difference should be required and quality of life endpoints should also be examined. The Committee also heard data regarding NDA 21-010, Epirubicin hydrochloride Injection, from Pharmacia & Upjohn Company, indicated for use as a component of adjuvant therapy in patients with evidence of axillary-node-tumor involvement following resection of primary breast cancer (Stage II & III), with locally advanced or metastatic breast cancer. The Committee voted that the safety risks were acceptable and that epirubicin was approvable in combination with cyclophosphamide and 5-FU for adjuvant treatment of patients with node-positive breast cancer. However, the Committee indicated that the data presented were not sufficient to provide independent substantiation for approval for epirubicin for first-line treatment of metastatic breast cancer. A letter was sent September 24, 1999.

On June 8, 1999, the Committee considered NDA 50-718, SE 006, Doxil® (doxorubicin HCl liposome injection), from Alza Corporation, indicated for the treatment of patients with metastatic carcinoma of the ovary who are refractory to both paclitaxel- and platinum-based chemotherapy regimens. Refractory is defined as a patient having progressive disease while on treatment, or within 6 months of completing treatment. The Committee relayed that complete responses to second line therapy are rare, and with an overall 13.8% response rate, it is unlikely that there will be any impact on survival data. Symptom control, or improvement in symptoms or in quality of life, would represent an advance in second line therapy for this indication. The Committee recommended approval and that further clinical trials to elucidate these endpoints be stipulated in any approval letter. An approval letter was issued June 30, 1999. The Committee also discussed NDA 20-221/ SE-012, Ethyol® (amifostine) for injection, U.S. Bioscience, Inc., indicated for use to reduce the incidence and severity of radiation induced xerostomia. The Committee felt that the data showed that Ethyol did not have a tumor protection effect, and that salivary function was protected. They voted 9-2 in favor of approval and the drug was approved on June 25, 1999.

On September 16, the Committee convened to discuss NDA 21-053, UFT (uracil and tegafur) capsules, from Bristol-Myers Squibb Company, indicated with leucovorin calcium tablets for the first-line treatment of metastatic colorectal cancer. The Committee felt that the UFT/LV regimen was shown to be equivalent to the active control and voted that, if the FDA concludes the contribution of uracil to UFT is adequately shown, the NDA is approvable. The Committee also heard data pertaining to NDA 50-772, Evacet™ (doxorubicin HCl liposome injection), from The Liposome Company, Inc., indicated for the first-line treatment of metastatic breast cancer in combination with cyclophosphamide. Although the pivotal trial showed equivalent response rates and similar survival, that result was not repeated in study 2, which compared single agent

Evacet vs. Adriamycin. In study 2, efficacy, as measured by response rate, did not meet the criteria and there was a trend towards decreased survival. The Committee indicated that, although the cardiotoxicity data were favorable for Evacet, the supportive studies did not have the statistical power to show equivalent efficacy in antitumor activity, and voted against approval. On September 17, 1999, the Committee heard presentations on NDA 20-262/S-033, Taxol® (paclitaxel) Injection, from Bristol-Myers Squibb Company, indicated for the adjuvant treatment of node-positive breast cancer administered sequentially to standard combination therapy. The Committee voted unanimously for approval for "all patients with node positive breast cancer" and a letter of approval was issued October 27, 1999. The Committee also considered biologics license application (BLA) 97-1001, Roferon®-A, Hoffman-La Roche Inc., indicated for use as adjuvant treatment of surgically resected malignant melanoma without clinical evidence of nodal disease, AJCC stage II (Breslow thickness > 1.5 mm, N0). The Committee expressed serious concerns about the quality of the data in this application, citing concerns about patient recruitment, the lack of appropriate stratification, the lack of a central pathology review, the accuracy of patient follow-up, and potential biases and voted unanimously against its approval.

Nov. 24, 1999
Date


Karen M. Templeton-Somers, Ph.D.
Executive Secretary

ONCOLOGIC DRUGS ADVISORY COMMITTEE

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ANNUAL REPORT
OF THE
MEDICAL DEVICES ADVISORY COMMITTEE

for the period

October 1, 1998 through September 30, 1999

Function

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the FFDC Act envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner of Food and Drugs regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of Food and Drugs on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between the FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The Panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

ANESTHESIOLOGY and RESPIRATORY THERAPY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met one time during the reporting period in Rockville, Maryland.

The date of the meeting was December 18, 1998.

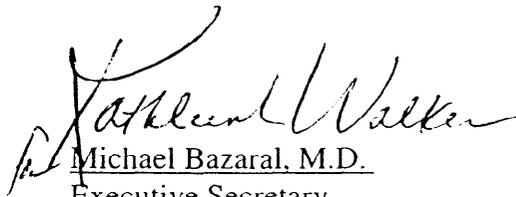
The meeting on December 18, 1998, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending issues and applications.

Accomplishments

On December 18, 1998, the panel met to discuss general issues related to tracheal gas insufflation (TGI) devices used to provide part or all of the breathing gas for treatment of respiratory insufficiency or failure. The use of TGI catheter, tube or lumen only for supply of fresh gas distinguishes TGI from common tracheal tubes and tracheostomy tubes, in which the gas flow alternates between inhalation and exhalation. Following the invited speaker's overview and two brief presentations on TGI, the panel identified the minimum function that would be included in a complete TGI system, and the risks that would need to be controlled. They also provided advice on the nature of the data that would be needed to evaluate a TGI system.

November 22, 1999

Date


Michael Bazaral, M.D.
Executive Secretary

WORK ADDRESS ROSTER
SORTED BY PANEL/COMMITTEE, FUNCTION, NAME

ANESTHESIOLOGY AND RESPIRATORY THERAPY DEVICES PANEL

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CIRCULATORY SYSTEM DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met three times during the reporting period in Gaithersburg, Maryland.

The dates of the meetings were October 27, 1998, December 7, 1998 and June 23-24, 1999.

No closed sessions were held during FY99.

ACCOMPLISHMENTS

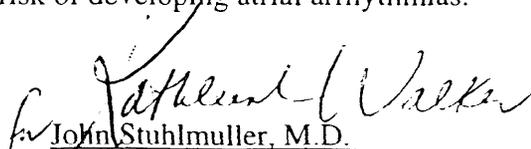
On October 27, 1998, a premarket approval application (PMA) for the Eclipse TMR Holmium Laser System was recommended for approval with conditions. The device is indicated for transmyocardial revascularization.

On December 7, 1998, the panel discussed and made recommendations on clinical trial requirements for future approval of coronary stents.

During the June 23-24, 1999 meeting, on the first day, a PMA for the EGS[®] and Ancure[®] Endovascular Grafting Systems was recommended for approval with conditions. These devices are indicated for treatment of Grade I and Grade II infrarenal abdominal aortic aneurysms. On the same day, another PMA for the AneuRx Bifurcated Endovascular Prosthesis System was recommended for approval with conditions. This device is indicated for the endovascular treatment of infrarenal abdominal aortic and aorto-iliac aneurysms. During the open public hearing, the Society for Vascular Surgery and the Lifeline Foundation presented information to the panel regarding post-market surveillance and physician training for these devices. On the second day, a PMA for the Hancock[®] II Bioprosthetic Heart Valve was recommended for approval with conditions. These devices are indicated for replacement of the aortic and/or mitral heart valves. On the same day, another PMA for the Model 7250 Jewel AF Arrhythmia Management Device was recommended for approval with conditions. The device is indicated for the treatment of patients who are at risk of sudden cardiac death due to ventricular arrhythmias that may also either have or are risk of developing atrial arrhythmias.

November 22, 1999

Date


John Stuhlmuller, M.D.
Executive Secretary

CIRCULATORY SYSTEM DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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CLINICAL CHEMISTRY and CLINICAL TOXICOLOGY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met one time during the reporting period in Gaithersburg, Maryland.

The date of the meeting was February 26, 1999.

The meeting on February 26, 1999, included a closed session to permit discussion and review of trade secret and/or confidential commercial information relating to present and future agency issues.

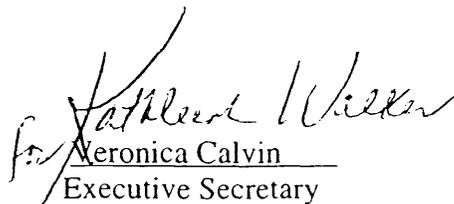
ACCOMPLISHMENTS

On February 26, 1999, a PMA for the continuous glucose monitoring system (CGMS) was recommended for approval with the following conditions: (1) submission of additional data analyses regarding interference validation of the calibration algorithm; (2) labeling changes and additional patient education information; (3) submission of additional data analyses regarding the validation of the calibration algorithm; and (4) additional studies to gather data from the use of the device in various patient groups not previously selected for study:

- a. Type II diabetics
- b. Children with diabetes
- c. Gestational onset of diabetes
- d. Long and short term duration diabetics; and
- e. Non-Caucasian diabetics

The device is intended to continuously record interstitial glucose levels in persons with diabetes mellitus. This information is intended to supplement not replace blood glucose monitoring devices. The information collected by CGMS may be down loaded and displayed on a computer and reviewed by healthcare professionals.

November 22, 1999
Date


for Xeronica Calvin
Executive Secretary

CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES PANEL

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DENTAL PRODUCTS PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met one time during the reporting period in Gaithersburg, Maryland.

The date of the meeting was May 10-11, 1999.

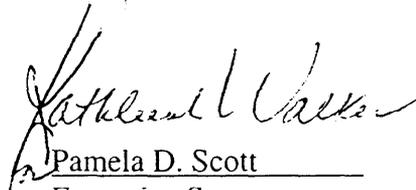
The meeting on May 10, 1999, included a closed session to permit discussion of trade secret and/or confidential information regarding dental device issues.

ACCOMPLISHMENTS

On May 10-11, 1999, the panel discussed two PMAs: Patient-Fitted TMJ Reconstruction Prosthesis and the TMJ Fossa Eminence/TMJ Condylar Prosthesis System. Both of these total temporomandibular joint (TMJ) prostheses are indicated for reconstruction of the TMJ. The panel recommended approval with conditions for both PMAs.

November 22, 1999

Date



Pamela D. Scott
Executive Secretary

DENTAL PRODUCTS PANEL OF THE MEDICAL DEVICE ADVISORY COMMITTEE

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EAR, NOSE, and THROAT DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met once during the reporting period in Rockville, Maryland.

The date of the meeting was June 18, 1999.

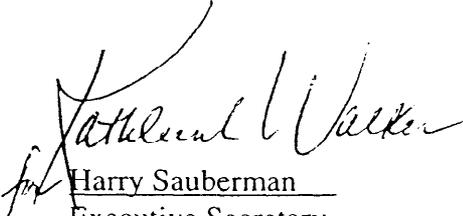
The meeting on June 18, 1999, included a closed session to permit discussion of trade secret and/or confidential commercial information relating to present and future agency issues.

ACCOMPLISHMENTS

On June 18, 1999, the panel met to discuss items relating to safety and efficacy of implantable middle ear amplification devices. The panel's suggestions and recommendations will be incorporated into a guidance document that manufacturers can follow when submitting IDEs or PMAs for these devices. A medical official from Health Canada participated as a guest expert, thus offering perspective from another regulatory body and enhancing the partnering initiative with the Canadian government.

November 22, 1999

Date


for Harry Sauberman
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EAR, NOSE AND THROAT DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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GASTROENTEROLOGY and UROLOGY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met two times during the reporting period in Rockville, Maryland.

The dates of the meetings were October 29, 1998 and July 29, 1999.

The meeting on ~~June~~^{July} 29, 1999, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding present and future FDA issues.

ACCOMPLISHMENTS

On October 29, 1998, the panel discussed a PMA Supplement for an extracorporeal immunoabsorption device. This new indication for the PROSORBA column is for the treatment of rheumatoid arthritis. The device was recommended for approval subject to the following conditions: 1) that the suggested modification be made to the labeling, including a revised statement of indications of use; and 2) a postmarketing study address device use in combination with other drugs to manage arthritis and rheumatoid arthritis diseases (DMARDs) and treatment with PROSORBA. If an indication of use for patients with mild rheumatoid arthritis is sought, a postmarketing study must also address this proposed indication.

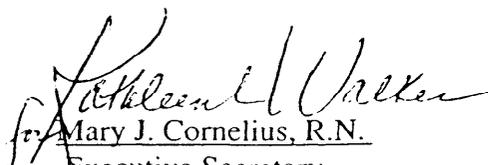
On July 29, 1999, a PMA for the Durasphere (urethral bulking agent) was recommended for approval subject to the following conditions:

1. labeling changes related to gender and child bearing age potential;
2. for use by physicians trained in therapeutic cystoscopy; and
3. post-approval study to follow 200 treated female patients for 5 years to evaluate long-term durability.

The device is indicated for the treatment of stress urinary incontinence due to intrinsic sphincter insufficiency. This device is injected into the urethral submucosa under endoscopic vision to achieve urethral bulking and coaptation. The panel also discussed possible revisions to the Draft Guidance for Preparation of PMAs for Testicular Prostheses, March 1993. The panel suggested the use of a patient registry as a long-term follow-up mechanism.

November 22, 1999

Date


for Mary J. Cornelius, R.N.
Executive Secretary

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GENERAL AND PLASTIC SURGERY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met twice during the reporting period in Rockville, Maryland and Gaithersburg, Maryland.

The dates of the meetings were November 17, 1998 and June 16, 1999.

The meeting on November 17, 1998, included a closed session to permit discussion of trade secret and/or confidential information regarding pending issues.

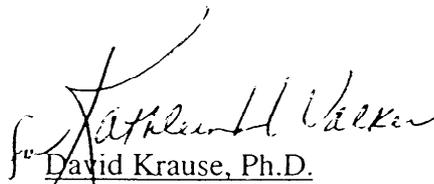
The meeting on June 16, 1999, included a closed presentation of data session to allow the sponsor to present to the committee trade secret and/or confidential commercial information.

ACCOMPLISHMENTS

On November 17, 1998, the panel recommended that hydrophilic wound and burn dressings, occlusive wound and burn dressings, hydrogel wound and burn dressings and cotton gauze be placed into class I. The panel also recommended that porcine burn dressings be placed into class II. Until this time all wound dressings were unclassified.

On June 16, 1999, a PMA for the Intuitive Surgical Endoscopic Instrument Control System and Intuitive Surgical Endoscopic Instrument was recommended for approval with conditions. These two conditions were: (1) that the company propose a comprehensive training program for proper training of surgeons intending to use the system; and (2) that the clip applier be removed from the list of approved instruments. This robotic system is currently intended for laparoscopic surgery.

November 22, 1999
Date


David Krause, Ph.D.
Executive Secretary

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GENERAL AND PLASTIC SURGERY DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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GENERAL HOSPITAL AND PERSONAL USE DEVICES PANEL

MEMBERSHIP

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MEETINGS

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The date of the meeting was August 2, 1999.

The meeting on August 2, 1999, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending and future submissions.

ACCOMPLISHMENTS

On August 2, 1999, the panel met to discuss possible revisions to the 1995 draft guidance "Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices with Sharps Injury Prevention Features." The panel recommended that clinical use studies be submitted for specific claims regarding reduction of sharps injuries. The panel also recommended the guidance document include more specifics on microbial test recommendations, evaluation of home-use products, and expanded emphasis on educational programs for users. The expanded use of post-market pilot studies was suggested by the panel. The panel also discussed and made recommendations for developing premarket guidance for jet injectors. They recommended the need for bench and preclinical information, with more extensive performance information for devices with new technology. The panel further recommended that the FDA should request data to determine the potential for cross-contamination with reusable injectors. The panel also suggested the need for prospective clinical data on administration of new vaccines and drugs and an analysis of existing data for drugs and biologics historically administered by these types of devices.

November 22, 1999
Date


for Martha O'Lone
Executive Secretary

GENERAL HOSPITAL AND PERSONAL USE DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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HEMATOLOGY and PATHOLOGY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met once during the reporting period in Gaithersburg, Maryland.

The date of the meeting was January 19-20, 1999.

On January 19, 1999, the committee heard and reviewed trade secret and/or confidential commercial information on a product development protocol (PDP). This portion of the meeting was closed to permit discussion of this information.

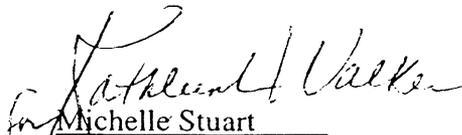
ACCOMPLISHMENTS

On January 19, 1999, following the open public session, the panel held its first discussion of a product development protocol.

On January 20, the panel recommended to the FDA that Class III automated differential cell counters be classified into Class II. The panelists identified the following special controls for the devices: testing guidelines, guidance documents and specific data labeling requirements for blast and atypical lymphocyte verification, bone marrow differential counts and progenitor cells.

November 22, 1999

Date


Michelle Stuart
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HEMATOLOGY AND PATHOLOGY DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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IMMUNOLOGY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met one time during the reporting period in Rockville, Maryland.

The date of the meeting was November 9, 1998.

The meeting on November 9, 1998, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending or future submissions.

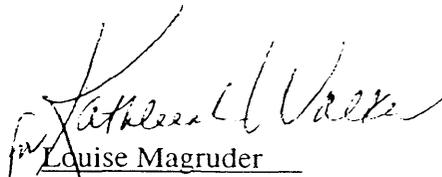
ACCOMPLISHMENTS

On November 9, 1998, a PMA for the PathVysion™ Her-2 DNA Probe Kit was recommended for approval subject to the following conditions:

- involve a pathologist in both the selection of the area of the slide to be read and the assay's interpretation;
- modify package insert to include reproducibility study and list of specimens that should be disqualified from testing; and
- include tissue samples as well as cell lines in user training and recommend periodic proficiency testing with tissue samples provided by the manufacturer.

The PathVysion™ Her-2 DNA Probe Kit (PathVysion Kit) is designed to detect amplification of the Her-2 gene via fluorescence in situ hybridization (FISH) in paraffin-embedded specimens from subjects with stage II, node positive breast cancer. Results from the PathVysion HER-2 Kit are intended for use as a rapid assessment of the potential response to Adriamycin (doxorubicin) containing therapy. The testing will be performed in CLIA high certified complexity laboratories.

November 22, 1999
Date


Louise Magruder
Executive Secretary

IMMUNOLOGY DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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MICROBIOLOGY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met once during the reporting period in Rockville, Maryland.

The date of the meeting was May 20-21, 1999.

The meeting on May 21, 1999, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending or future submissions.

ACCOMPLISHMENT

On May 20-21, 1999, the panel discussed a 510(k) submission for the Hybrid Capture CMB Nucleic Acid Hybridization Assay for the Chemiluminescent Detection of Cytomegalovirus (CMV) DNA in white blood cells. The focus of the discussion was on the use of signal amplification terminology. The panel recommended two choices: (1) signal amplified nucleic acid hybridization assay and (2) nucleic acid hybridization assay with signal amplification. On the same day, the panel discussed a PMA Supplement for the Amplified Mycobacterium Tuberculosis Direct (Mtd) Test sponsored by Gen Probe. This is a target-amplified nucleic acid probe test with a new indication for the detection of *Mycobacterium tuberculosis* complex in sediments prepared from sputum (induced or expectorated), bronchial specimens, or tracheal aspirates from patients with smear negative respiratory sediments. The panel recommended that the PMA supplement be approved with conditions. The conditions were: (1) a graph showing prevalence effects on positive predictive values and guidance for interpreting be included in the package insert; (2) a warning statement to indicate that study data were based on a population with a prevalence of 11%; (3) positive MTD results for smear negative patients must be confirmed by culture; (4) separate performance representations for smear negative and smear positive patients; (5) ninety-five percent confidence bands be included in the analysis of predictive value; (6) post-approval studies should be conducted to assess the prevalence effects on test performance; and (7) interpretation of MTD results for smear negative patients should consider pretest probabilities.

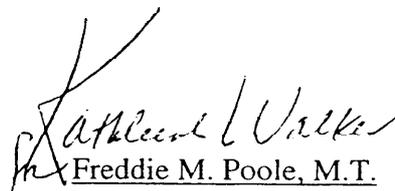
On the second day, the panel discussed two PMAs. The first PMA is for the Biotrin Parvovirus B19 IgG enzyme immunoassay (EIA), a qualitative device to detect IgG antibodies to Parvovirus B19 in human serum and plasma. The IgG test is indicated for use in all women where there is a suspicion of exposure to Parvovirus B19 as a marker of previous infection. The second PMA is for the Biotrin Parvovirus B19 IgM EIA, a qualitative device to detect IgM antibodies to Parvovirus B19 in serum and plasma. The IgM test is indicated for use in conjunction with the Parvovirus B19 IgG EIA for the testing of pregnant women who have sonographic evidence of abnormal fetal development and to determine immunological status during the first trimester of

Page 2 – Microbiology Devices Panel (continued)

pregnancy. The panel recommended that both PMAs be approved with conditions. These conditions were: (1) that the intended use statement be expanded to include for use with fifth disease (erythema infectiosum) and CDC data be included; (2) that the interpretation of results be modified to include a warning of interpretation with clinical symptoms; (3) that confidence intervals be reported with sensitivity data; and (4) that appropriate limitation statements be included.

November 22, 1999

Date


Freddie M. Poole, M.T.
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NEUROLOGICAL DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met once during the reporting period in Rockville, Maryland.

The date of the meeting was September 16-17, 1999.

The meeting on September 17, 1999, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding present and future FDA issues.

ACCOMPLISHMENTS

On September 16-17, 1999, the panel met to discuss the draft guidance document for Dura Substitute Devices and made suggestions to FDA on some aspects of the clinical study requirements for new dura substitute devices, including appropriate imaging techniques, control groups, and the sources of animal derived tissue (from U.S. versus non-U.S. sources). The panelists recommended that human dura mater intended to replace or repair dura mater be classified into class II. They identified the following as potential special controls to reasonably assure the safety and effectiveness of the device: (1) FDA guidances, (2) postmarket surveillance, (3) patient registries, (4) device tracking; and (5) restrictions on donor screening. On the second day, of the same meeting, the panel met to discuss the draft guidance document for Neurological Embolization Devices and made suggestions to the agency on some aspects of the clinical study requirements for new neurological embolization devices, including appropriate study end points, follow-up times, and imaging methods. In addition, the panel recommended that the postamendment class III totally implanted spinal cord stimulator for pain relief be reclassified into class II. The panel identified the following as potential special controls to reasonably assure the safety and effectiveness of the device: FDA guidances, voluntary consensus standards, postmarket surveillance, patient registries, device tracking, biennial manufacturing site inspections, and submission of annual reports on device failures.

November 22, 1999

Date


Van Scudiero
Executive Secretary

NEUROLOGICAL DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

EXECUTIVE SECRETARY

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OBSTETRICS and GYNECOLOGY DEVICES PANEL

MEMBERSHIP

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MEETINGS

The panel met once during the reporting period in Rockville, Maryland.

The dates of the meeting were October 19-20, 1998.

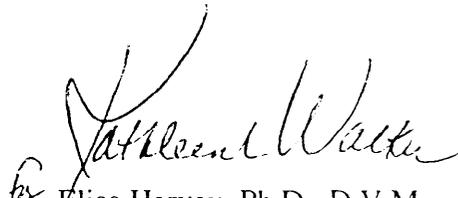
The meeting on October 19, 1998, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending issues.

ACCOMPLISHMENTS

On October 19, 1998, the panel discussed a PMA for the Vestablate™ Thermal Endometrial Ablation System. The device is intended to treat premenopausal women with abnormal uterine bleeding. After deliberations, the panel recommended approval of the PMA subject to conditions. On October 20, in the context of the current guidance document on thermal endometrial ablation devices, the panel discussed initial safety studies as well as the pivotal safety and effectiveness study for postmenopausal patients on hormone replacement therapy, which will include inclusion/exclusion criteria, types of control and length of follow-up, both premarket and postmarket. The panel also addressed proposed labeling for vacuum-assisted delivery devices.

November 22, 1999

Date


for Elisa Harvey, Ph.D., D.V.M.
Executive Secretary

OBSTETRICS AND GYNECOLOGY DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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OPHTHALMIC DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met four times during the reporting period in Gaithersburg, Maryland; Rockville, Maryland and Silver Spring, Maryland.

The dates of the meetings were October 22-23, 1998; January 12, 1999; July 22-23, 1999 and September 23, 1999.

The meeting on October 22, 1998, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending issues and applications.

ACCOMPLISHMENTS

On October 22-23, 1998, the panel discussed issues related to the development of extensions to the guidance document for refractive surgical lasers to include the clinical criteria for the determination of safety and effectiveness for photorefractive keratectomy (PRK) and laser in-situ keratomileusis (LASIK) for myopia and hyperopia with and without astigmatism, presbyopia, and other refractive indications. On the second day the panel discussed issues related to the preliminary development of guidance for refractive implants (phakic intraocular lenses and corneal implants) to include clinical design and development.

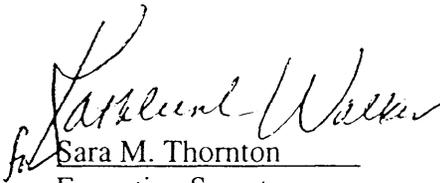
On January 12, 1999, a PMA for the Intrastromal Corneal Ring was recommended for approval with conditions related to labeling and continued follow-up (to 2 years needed on a specific population). The ring is designed for the correction of myopia from -1.00 to -3.50 diopters in patients having 1.0 diopter or less astigmatism.

On July 22-23, 1999, a PMA Supplement and three PMAs were discussed: a PMA Supplement for the SVS Apex Plus Excimer Laser Workstation was recommended for approval with conditions. The first PMA for the Visx Excimer Laser System Model C "Star" was recommended for approval with conditions relating to limit on indications and labeling issues. These devices are indicated for the correction of moderate to high myopia with or without astigmatism using LASIK. The second PMA for the Hyperion LTK System was recommended for non-approval. This device is indicated for the correction of hyperopia using laser thermal keratomileusis (LTK). The third PMA for the Hydroview Composite Hydrogel Foldable UV Absorbing Posterior Chamber Intraocular Lens (IOL) was recommended for approval with conditions. Those conditions include labeling changes. The device is indicated for primary implantation for the visual correction of aphakia after cataract extraction.

Page 2 - Ophthalmic Devices Panel (continued)

On September 23, 1999, the panel had a group discussion with public participation in an attempt to develop a comprehensive list of problems associated with keratomes, related causes, and the steps that can be taken to mitigate the problems. The panel also deliberated on issues related to defining the scope and purpose of a proposed keratome guidance to be developed from an outline of contents currently recommended for keratome premarket notification submissions.

November 22, 1999
Date


Sara M. Thornton
Executive Secretary

OPHTHALMIC DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE

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ORTHOPAEDIC and REHABILITATION DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met twice during the reporting period in Rockville, Maryland and Gaithersburg, Maryland.

The dates of the meetings were October 8-9, 1998 and July 26, 1999.

The meeting on October 8, 1998, included a closed presentation of data session to allow the committee to hear and review trade secret and/or confidential commercial information on investigational device exemptions. A closed session was held to permit discussion of trade secret information and/or confidential commercial information regarding present and future FDA issues.

On July 26, 1999, closed committee deliberations were held during which the panel discussed and made recommendations on a product development protocol (PDP). The session was closed because the panel heard and reviewed trade secret and/or confidential commercial information as part of the PDP.

ACCOMPLISHMENTS

On October 8, 1998, in the morning during the closed presentation of data session, the panel heard and reviewed trade secret and/or confidential commercial information on investigational device exemptions (IDEs). In the open session, the panel discussed a preliminary background document pertaining to the development of IDE for spinal device assemblies. The following were issues of concern: (1) outcome measures; (2) radiographic end points for fusion using X-ray, CT scans, and MRI; (3) study designs and statistical model used in spinal clinical studies; (4) end points for the study intended to assess the efficacy and safety of the device including spinal fusion, function, pain, and overall quality of life. On October 9, the panel discussed a PMA for the Norian SRS Cancellous Bone Cement. This device is indicated for fracture stabilization and for cancellous bone replacement in the treatment of fracture defects of the distal radius. After deliberations they identified necessary measures to place the application in an approvable form subject to the following conditions:

- A more limited indication statement for the device was identified to be incorporated into the device labeling.
- Among the safety issues discussed were the reports of intra-articular bone cement, the unknown long term effects of the material, and the reported loss of radial length. It was noted that the labeling should address each of these concerns.

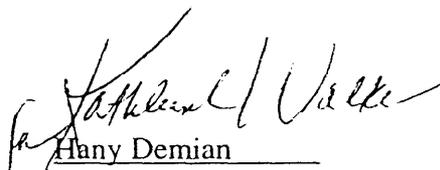
Page 2 - Orthopaedic and Rehabilitation Devices Panel (continued)

- Post-approval study requirements were discussed. These included specified continued follow-up on all patients and specified longer follow-up on those patients with intra-articular bone cement.
- A provision for a training program for physicians was discussed.

On July 26, 1999, after an open public session, the panel met in a closed session to discuss and make recommendations on two PDPs for mobile bearing knees.

November 22, 1999

Date


Hany Demian
Executive Secretary

ORTHOPAEDIC AND REHABILITATION DEVICES PANEL OF THE MEDICAL
DEVICES ADVISORY COMMITTEE, FDA

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RADIOLOGICAL DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met once during the reporting period in Rockville, Maryland.

The date of the meeting was May 17, 1999.

The meeting on May 17, 1999, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding present and future FDA issues.

ACCOMPLISHMENTS

On May 17, 1999, the panel met to discuss and make recommendations on bone strength assessment, with a focus on the use of gender and race specific databases in assessing fracture risk, and their applicability to bone densitometry and sonometry device labeling and output. Seven speakers from the medical and academic communities made presentations including the basis for the currently used bone assessment paradigms and the strengths and weaknesses of the various measurement parameters. Four speakers from industry described various methods for reporting the results of bone strength assessments. The presentations were followed by a discussion period after which the members of the panel made eight recommendations that will be considered when reviewing future bone densitometry device submissions.

November 22, 1999

Date


Robert Doyle
Executive Secretary

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Annual Report
Of the

Science Advisory Board to the National Center for Toxicological research

Food and Drug Administration
Rockville, MD 20857

For the period

October 1, 1998 through September 30, 1999

FUNCTION

The Board advises the Director, NCTR, in establishing, implementing and evaluating the research programs that assist the Commissioner of Food and Drugs in fulfilling his/her regulatory responsibilities. The Board provides an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met one time during the reporting period in Jefferson, AR.

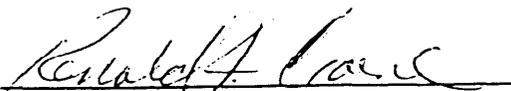
The dates of the meeting were April 26-27, 1999.

The meeting on April 27 included a closed session to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy. (5 U.S.C. 552b (c) (6)). The Board discussed qualifications and performance of individuals associated with the research programs at the Center that had undergone review.

ACCOMPLISHMENTS

At the meeting the Board was presented with, and approved draft reports, from the site visit chairs, on three of the Centers research programs, Endocrine Disrupter Knowledge Base projects and the Divisions of Genetic Toxicology and Molecular Epidemiology, including recommendations. Following the presentation the Center Director instructed the Directors of these three programs to prepare a response to the report, including a progress report on the implementation of their recommendations, for presentation at the next full Board meeting. The directors of the Biometry and Risk Assessment, and the Neurotoxicology Programs provided an update to the Board on the actions they'd taken relative the site visit teams recommendations.

Date: 11/29/99


Ronald F. Coene, P.E.
Executive Secretary

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ANNUAL REPORT
OF THE
SCIENCE BOARD TO THE FOOD AND DRUG ADMINISTRATION

for the period

October 1, 1998 through September 30, 1999

FUNCTION

The Board shall provide advice primarily to the Agency's Senior Science Advisor, the Commissioner, and other appropriate officials on specific complex and technical issues as well as emerging issues with the scientific community, industry, and academia. Additionally, the Board will provide advice to the Agency on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of Agency sponsored intramural and extramural scientific research programs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met one time during the reporting period at the Washington Plaza Hotel, Washington Room, 10 Thomas Circle, N.W., Washington, D.C.

The date of this meeting was October 21, 1998.

The meeting on October 21, 1998 included a closed session to permit discussion of 1998 FDA Scientific Achievement Awards, and science and research programs.

ACCOMPLISHMENTS

The Science Board approved the report, "Review of Research Programs of the Center for Biologics Evaluation and Research", and agreed that the report be submitted to the FDA for use by the Center. Further, it was recommended that the process used for the CBER review be used as a model for programmatic review of research by other components of the Agency.

Dr. Elkan Blout, Senior Advisor for Science, Dr. David Kipnis, Chair, Search Committee for the Chief Scientist and Dr. Michael Friedman, Acting Commissioner of Food and Drugs, provided comments on the recruitment and role of the Chief Scientist for the Agency (a recommendation of the Science Board Subcommittee on FDA Research).

Dr. Bernard Schwetz, Interim Chief Scientist, discussed plans within the Office of Science to raise the awareness of the culture of science within the Agency, to increase responsiveness to issues of high priority, to coordinate and integrate resources to identify and address high priority issues, and to develop further support for the Agency's science programs.

Dr. Alan Rulis, Acting Deputy Director for Programs from the Center for Food Safety and Applied Nutrition, presented an overview of the Center's research programs. The Science Board recommended the development of a subcommittee to conduct the programmatic review and requested a synopsis of the findings to be presented at the next meeting of the Science Board.

Dr. Sam Page, Center for Food Safety and Applied Nutrition presented a brief overview of the programs of the Joint Institute for Food Safety and Nutrition, a Center established under the Food Safety Initiative.

Dr. Gilbert Leveille and Dr. Marion Nestle, members of the Science Board, were requested to participate and provide guidance to the review process of research at the Center for Food Safety and Applied Nutrition.

Recommendations

- Report on the review of research programs at the Center for Biologics Evaluation and Research – Based upon agreed-upon comments of the members of the Science Board, and the report of the Subcommittee for the CBER review will be transmitted to the Agency.
- Peer Review Process – The Science Board endorsed the formation of a subcommittee to conduct a programmatic review of the research programs of the Center for Food Safety and Applied Nutrition and prepare a summary report for presentation at the next Science Board meeting. Further, the Science Board again endorsed the continued review of the remaining components of the Agency.
- Statement of Support for FDA Science – It was recommended that the Science Board prepare a statement of support for FDA science and research to be considered in discussions regarding additional funding for Federal science programs.

Closed Committee deliberations – On October 21, 1998, 9:00 – 10:00 a.m., the meeting was closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b (c) (6)). The Board discussed nominations for the FDA Awards for Scientific Achievement. Such discussion in a public meeting would disclose information of a personal nature and would constitute an invasion of personal privacy.

11/19/99

November 19, 1999
Date

Susan A. Homire

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(Typed name)
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**SCIENCE BOARD
TO THE
FOOD AND DRUG ADMINISTRATION**

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Current through December 31, 1998



ANNUAL REPORT
OF THE
BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE
for the period
October 1, 1999 though September 30, 2000

FUNCTION

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of biological response modifiers which are intended for use in the prevention and treatment of a broad spectrum of human diseases. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met three times during the reporting period including a meeting of the Xenotransplantation Subcommittee. Meetings were held in Gaithersburg, Maryland and Bethesda, Maryland.

The dates of those meetings were: January 13, 2000; March 20-21, 2000; and July 13-14, 2000.

The meeting on March 20-21, 2000 included a closed session to permit discussion of matters of a personal nature.

ACCOMPLISHMENTS

At the January 13, 2000 meeting:

In open session, the Xenotransplantation Subcommittee of the Biological Response Modifiers Advisory Committee discussed and made recommendations regarding issues related to deferral of blood donations from xenotransplant recipients and the risk posed by different models of xenotransplantation products. The Committee also recommended that xenotransplant recipients be indefinitely deferred from blood donation and that whole blood, unpooled blood components and plasma derivatives from xenotransplant recipients be withdrawn from donation.

At the March 20-21, 2000 meeting:

In open session, the Committee reviewed, discussed and accepted the recommendations of the Xenotransplantation Subcommittee regarding issues related to deferral of blood donations from xenotransplant recipients and the risk posed by different models of xenotransplantation products. The Committee approved the Xenotransplantation Subcommittee recommendation that xenotransplant recipients be indefinitely deferred from blood donation and that whole blood, unpooled blood components and plasma derivatives from xenotransplant recipients be withdrawn from donation.

The Committee also discussed the role of animal studies in the development of protein therapeutics. The Committee recommended that animal studies, particularly primate studies should be indicated by the extent of the immunogenicity concerns related to a particular biologic/therapeutic therapy.

The Committee discussed the appropriate role for antibody assays in product development. The Committee recommended that sponsors test all patients in clinical studies with sensitive assays for total antibody and, where relevant, neutralizing antibody prior to applying for marketing authorization.

The Committee discussed the use of pancreatic islets for the treatment of diabetes. The Committee made recommendations related to the procurement, processing and characterization of islets. The Committee made recommendations related to preclinical studies of immunosuppressive regimens, donor-recipient matching, route and site of islet product administration and clinical trial outcome measures.

In closed session, the Committee recommended personnel and program actions for the Laboratory of Chemistry, Division of Therapeutic Proteins, the Laboratory of Cytokine Research and the Laboratory of Cell Biology, Division of Cytokine Biology. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal

privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

At the July 13-14, 2000 meeting:

In open session, the Committee discussed product development issues related to human stem cells as cellular replacement therapies for neurological disorders. The Committee made recommendations concerning product development issues including human stem cell sources, characterization of stem cell preparations and potency assays for stem cell products. The Committee made recommendations concerning preclinical pharmacology and toxicology issues including selection of the most appropriate animal models, tumorigenicity, cell migration, differentiation and survival.

10-31-00

Date

Gail M. Dapolito

Gail M. Dapolito
Executive Secretary

**BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION**

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ANNUAL REPORT
OF THE
BLOOD PRODUCTS ADVISORY COMMITTEE
for the period

October 1, 1999 through September 30, 2000

FUNCTION

The committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases and advises the Commissioner of Food and Drugs of its findings regarding the safety, effectiveness, and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological product licenses, and on the quality and relevance of FDA's research program which provides the scientific support for regulating these agents. The committee functions at times as a medical device panel under the Medical Device Amendments of 1976.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met three times during the reporting period in Silver Spring, Maryland and Gaithersburg, Maryland. The dates of those meetings were: March 15-17, 2000, June 15-16, 2000, and September 14-15, 2000. The meetings on March 16-17, 2000 and September 14-15, 2000 were partially closed to permit discussion of trade secret or confidential commercial information relevant to pending license applications or personal information relevant to the scientific site visit reviews, respectively (5 U.S.C. 552b(c)(4) and (6)).

ACCOMPLISHMENTS

- I. The March 16-17, 2000 meeting included:
 - A. Summary updates of recent workshops on Bacterial Contamination of Platelets, Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Cell Substitutes, Implementation of Universal

Leukoreduction and Parvovirus B19; and a summary of the PHS Advisory Committee meeting on Blood Safety and Availability, CJD Policy, HCV Lookback Guidance, Post Donation Information Algorithm, and IGIV Clinical Endpoints.

- B. Discussion and recommendations on indeterminate HIV-1 Western blots with only non-viral bands.

Agency action: In process.

- C. Discussion and recommendations on History of Hepatitis.

- D. Discussion and recommendations on HBV Nucleic Acid testing.

Agency action: In process.

- E. Donor deferral issues related to xenotransplantation.

Agency action: Draft guidance to industry in preparation.

- F. The committee reviewed and evaluated the intramural research program of the Laboratory of Plasma Derivatives, Division of Hematology, Office of Blood Research and Review.

- G. In closed session, the committee recommended personnel and program actions for the Laboratory of Plasma Derivatives. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6).

II. The June 15-16, 2000 committee meeting included:

- A. Committees updates on the PHS Advisory Committee on Blood Safety and Availability, Summary of Workshop on Plasticizers: Scientific Issues in Blood Collection, Storage, and Transfusion, Report on Blood Supply Monitoring, Summary of Transmissible Spongiform Encephalopathies Advisory Committee Meeting, Requirement for Syphilis Testing, Regulation of HIV Drug Resistance Tests, Risk of HCV to Sexual Partners and Relative Sensitivity of HBsAg and HBV NAT Tests.

- B. Discussion and recommendations on Plasma Pool Screening by Nucleic Acid Tests for Hepatitis A Virus

- C. Discussion and recommendations on the Development of Rapid HIV Tests.

Agency action: In process.

- D. Discussion and recommendations on Proposed FDA Guidance on Leukoreduction: Current Thinking.

Agency action: Draft guidance for industry in process.

III. The September 14-15, 2000 committee meeting included:

- A. Committee updates on summaries of PHS Advisory Committee on Blood Safety and Availability and Joint Transmissible Spongiform Encephalopathies and Vaccines and Related Biological Products Advisory Committees meeting, Factor VIII & vWF Standards, Blood Supply, Donor Questionnaire, Rapid HIV Test Approval Requirements and Standards, Summaries of Workshops on Recruiting Blood Donors, Hemopoietic Cells From Cord Blood, and Public Meeting on Regulation of Bone Products.

- B. Discussion and recommendations on HIV p24 Antigen Testing of Plasma for Fractionation - Potential Criteria for Discontinuation.

Agency action: In process.

- C. Discussion and recommendations on Deferral, as Blood or Plasma Donors, of Males Who Have Had Sex with Males.

Agency action: Draft guidance preparation in process.

- D. Discussion and recommendations on Current Utility of Screening Blood Donors for Antibodies to Syphilis.

Agency action: Preparation for publishing of final rule for testing for infectious disease of blood and plasma donors.

- E. Discussion and recommendations on Classification of HLA Devices.

Agency action: In process.

- F. The committee reviewed and evaluated the intramural research program of the Laboratory of Molecular Virology, Division of Emerging and Transfusion Transmitted Diseases, Office of Blood Research and Review.

- G. In closed session, the committee recommended personnel and program actions for the Laboratory of Molecular Virology. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6).

11/27/00
Date

Linda A. Smallwood
Linda A. Smallwood, Ph.D.
Executive Secretary

**BLOOD PRODUCTS ADVISORY COMMITTEE
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH**

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ANNUAL REPORT
OF THE
TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ADVISORY
COMMITTEE

for the period

October 1, 1999 through September 30, 2000

FUNCTION

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 as determined by the Commissioner of Food and Drugs. The Committee will make recommendations to the Commissioner regarding the regulation of such products.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Committee met twice during the reporting period in Gaithersburg, Maryland and Bethesda, Maryland. The dates of those meetings were June 1 & 2, 2000 and July 27, 2000.

The July 27, 2000 meeting included a closed session to permit discussion of trade secret and confidential commercial information.

ACCOMPLISHMENTS

June 1 & 2, 2000 Meeting

1. In open session the Committee reviewed and discussed new information concerning transmissible spongiform encephalopathies (TSE) in other countries and then made recommendations regarding the current FDA policy on deferral of blood and plasma donors based on the donor's history of travel or residence in the UK and other countries.
2. The Committee discussed leukoreduction of blood and the possible implications this process could have with regards to the theoretical risk of transmission of Creutzfeldt-Jakob Disease (CJD).

July 27, 2000 Meeting

1. In open session the Committee discussed and made recommendations on appropriate precautions to be taken with regard to the use of bovine-derived materials in the manufacture of vaccines when those materials were obtained from countries in which bovine spongiform encephalopathy (BSE) is known to exist. The agency used the Committee recommendations for direction and guidance.
2. In closed session the Committee discussed trade secret and confidential commercial information related to a development and manufacture of vaccines (5 U.S.C. 552b(c)(4)).

10/31/00
Date

William Freas
William Freas, Ph.D.
Executive Secretary

**TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ADVISORY COMMITTEE
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH**

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Revised 7/12/00



ANNUAL REPORT
OF THE
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
for the period

October 1, 1999 through September 30, 2000

FUNCTION

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met five times during the reporting period. Meetings were held in Bethesda, Maryland and Silver Spring, Maryland. One meeting was held by teleconference.

The dates of those meetings were November 4-5, 1999; January 27-28, 2000; March 10, 2000; May 10, 2000; and July 27, 2000.

The meetings on November 4 and November 5, 1999, and on January 28, May 11, and May 12, 2000 included closed sessions to permit discussion of trade secret or confidential commercial information or matters of a personal nature.

ACCOMPLISHMENTS

At the November 4-5, 1999 meeting:

1. In closed session, the committee discussed a viral product under development. The discussion included trade secret or confidential commercial information.

2. The committee heard a short briefing on the Public Citizen suit and settlement affecting release of briefing materials to the public before or at the time of the advisory committee meeting.
3. The committee discussed a proposal from NIAID for Phase I clinical testing of a novel human cytomegalovirus live vaccine. No votes were taken.
4. In closed session, the committee was briefed on trade secret or confidential commercial information pertaining to a proposed supplemental application for a licensed product.
5. The committee considered data on reactogenicity of a 5th successive dose of Pasteur Merieux Connaught's licensed DTaP vaccine, Tripedia. No votes were taken, but the committee members generally agreed that the vaccine was approvable for a 5th successive dose. The vaccine was approved for the 5th dose on August 24, 2000.
6. In closed session, the committee was briefed on manufacturing issues concerning a product undergoing review for licensure. The discussion included trade secret and confidential commercial information.
7. The committee reviewed data pertaining to the safety and efficacy of Wyeth Lederle's pneumococcal 7-valent conjugate vaccine, Prevenar, for the prevention of meningitis and invasive disease. The vaccine was approved by FDA for use in infants on February 17, 2000.

At the January 27-28, 2000 meeting:

1. The advisory committee commented on the current understanding of immune correlates of protection against invasive Haemophilus influenza b (Hib) disease and the clinical significance of reduced antibody response to Hib polysaccharide when combined with DTaP vaccine or administered concurrently. No votes were taken.
2. The committee recommended that the viral influenza vaccine for the coming season should, as in previous years, be a trivalent one, and that the influenza A H1N1 antigen be changed from that contained in the previous year's formulation.
3. The committee heard a briefing on selected activities within the Laboratory of Pediatric and Respiratory Virus Diseases.
4. In closed session, the committee recommended personnel and program actions for the Laboratory of Pediatric and Respiratory Virus Diseases. Disclosure of the information during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). These recommendations were used by FDA as part of its independent intramural program review.

At the March 10, 2000 meeting:

1. The committee completed its recommendation on the composition of the influenza virus vaccine for the 1999-2000 season, advising that the A H3N2 strain be changed to a newer one and that the current B strain be retained from the previous year's formulation.

2. The committee was updated on the Vaccine Safety Action Plan which has been delegated to the National Vaccine Program Office for implementation. Although FDA intended this session as a briefing only, the committee voted to endorse the plan and support the need for stable funding.

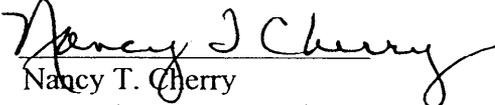
At the May 11-12, 2000 meeting:

1. In closed session, the committee met to hear a briefing on manufacturing issues related to a product under development. This session included trade secret or confidential commercial information.
2. The committee was briefed on recent activities in the Office of Vaccines Research and Review pertaining to vaccine safety, including conferences on use of thimerosal and aluminum in vaccines, initiation of programs to counter bioterrorism, and efforts to ascertain the presence of SV40 in oral polio vaccine.
3. The committee reviewed and commented on available safety information on rotavirus vaccines and vaccine candidates, particularly the relationship between rotavirus vaccination and development of the adverse event, intussusception. No votes were taken.
4. In closed session, the committee met to discuss a product under development. The discussion included trade secret or confidential commercial information.
5. In closed session, the committee heard a briefing on products under development. Trade secret and/or confidential commercial information was included in the session.
6. The committee discussed CBER's draft proposals for the use of different types of neoplastic cells as substrates for vaccine manufacture. No votes were taken.

At the July 27, 2000 meeting:

1. In closed session, with the Transmissible Spongiform Encephalopathy Committee, the committee heard manufacturers discuss trade secret or company confidential material pertaining to the manufacture of vaccines. These presentations provided the committee with background information for the open committee discussion to follow.
2. The committee met in joint session with the Transmissible Spongiform Encephalopathy committee to consider appropriate precautions to be taken with regard to use of bovine-derived materials in the manufacture of vaccines when those materials were obtained from countries in which bovine spongiform encephalopathy (BSE) is known to exist or from countries where the USDA has been unable to assure the FDA that BSE does not exist. The committee was also asked to consider potential risks and possible actions to be taken with regard to licensed or investigational vaccine products that may be affected. No votes were taken.

Oct 26, 2000
Date


Nancy T. Cherry
Executive Secretary

**VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH**

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ANNUAL REPORT
of the
ANTIVIRAL DRUGS ADVISORY COMMITTEE
for the period
October 1, 1999 through September 30, 2000

FUNCTION

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 acquired immune deficiency syndrome (AIDS), HIV-related illnesses, and other viral, fungal, and mycobacterial infections, and makes appropriate recommendations to the Commissioner of Food and Drugs. The Committee also provides critical review of agency sponsored intramural and extramural research programs in support of the FDA's regulatory functions.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Committee met three times during the reporting period in Gaithersburg, Maryland. The dates of those meetings were October 4 and 5, 1999, November 1, 2, and 3, 1999, and July 25 and 26, 2000.

The meetings on October 4 and 5, 1999, and July 26, 2000 included a closed session to permit discussion of trade secret and/or confidential commercial information.

ACCOMPLISHMENTS

On October 4, 1999, during the morning session the Committee discussed issues related to the potential applicability of information from non-U.S. studies of prevention of perinatal HIV (Human Immunodeficiency Virus) transmission to U.S. clinical settings.

Presentations were made regarding the epidemiology of mother-to-child transmission of HIV in the U.S. and the USPHS task force recommendations. An overview of NICHHD/CRMC/PAMA clinical trials was presented. The CDC presented information on the conduct of trials in developing nations. The FDA presented information on the safety considerations on conducting these clinical trials and the regulatory considerations in the development of drugs to prevent perinatal transmission of HIV. During the afternoon session on October 4, 1999 and on October 5, 1999 the Committee met in closed session to discuss confidential commercial information relevant to pending investigational new drug applications and drug development plans.

On November 1, 1999, the Committee discussed NDA 20-993, adefovir dipivoxil, Gilead Sciences Incorporated, for the treatment of HIV (human immunodeficiency virus) infection. The majority of the Committee agreed that the data did not establish the safety and efficacy of the 60mg dose. Additional suggestions for further investigation included studies of population subsets (race, gender, and HBV/HIV coinfection), drug interactions, PK/PD, resistance, and safety. The Committee recommended against approval. FDA did not approve the drug.

On November 2 and 3, 1999, the Committee met to discuss issues related to testing for development of resistant Human Immunodeficiency Virus (HIV-1), with an emphasis on its potential role in antiretroviral drug development. The Committee provided advice and recommendations on the amount and type of resistance data needed to support both preclinical and clinical development of antiretroviral drugs and antiretroviral product labeling.

On July 25, 2000, the Committee met to discuss scientific data characterizing relationships of pharmacokinetic parameters and virologic response to approved antiretroviral drugs used in the treatment of HIV infection. Committee deliberations explored the use of pharmacokinetic data to improve the evaluation of new formulations, alternative dosing regimens, and choice of dosing in the setting of drug-drug interactions for approved antiretroviral drugs. Other issues discussed include the relationship between pharmacokinetic (PK) parameters and drug toxicity; and safety requirements and pediatric considerations for alternative dosing regimens. A number of recommendations were made which included the need for additional studies to relate specific PK parameters with virologic outcome and safety, and therapeutic drug monitoring.

On July 26, 2000, the Committee met in closed session for a briefing on pending investigational new drug applications (INDs), drug development plans, and an update on recent action on selected new drug applications (NDAs) in the Division of Antiviral Drug Products and the Division of Special Pathogen and Immunologic Drug Products.

1-17-01
Date


Tara P. Turner, Pharm.D.
Executive Secretary

**ANTIVIRAL DRUGS ADVISORY COMMITTEE
CENTER FOR DRUG EVALUATION AND RESEARCH**

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**Annual Report
of the
Arthritis Advisory Committee
for the period
October 1, 1999 through September 30, 2000**

Function

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases, and makes appropriate recommendations to the Commissioner of Food and Drugs.

Membership

A roster of members is attached.

Meetings

The Committee met twice during the reporting period in Rockville, Maryland. The dates of those meetings were April 11, 2000, and July 12, 2000. A portion of the meeting on April 11, 2000, was held in closed session to permit the discussion of trade secret and/or confidential commercial information.

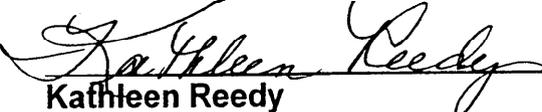
Accomplishments

On April 11, 2000, the Committee met to discuss biologics license application (BLA) 99-0884, Enbrel™ (etanercept) Immunex, already approved for the treatment of signs and symptoms rheumatoid arthritis in adults, for an indication for the treatment of patients with early stage rheumatoid arthritis, the first or second year. The Committee recommended the approval of the expanded indication for the approved product. The Committee met in closed session for the rest of the day.

The Committee met on July 12, 2000, to discuss BLA 99-1234, Remicade™ (infliximab) Centocor, already approved for the treatment of signs and symptoms of rheumatoid arthritis, for the prevention of radiographic progression and prevention of physical disability. The Committee also discussed general issues regarding claims based on radiographic data in patients with rheumatoid arthritis. The

Committee recommended general criteria for a claim referring to radiographic progression, and the limited adoption of the expansion of the indication of the Centocor product for labeling. The agency has modified the label.

12/6/01
Date


Kathleen Reedy
Executive Secretary

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CENTER FOR DRUG EVALUATION AND RESEARCH**

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ANNUAL REPORT
of the
DERMATOLOGIC AND OPHTHALMIC DRUGS ADVISORY COMMITTEE
for the period
October 1, 1999 through September 30, 2000

FUNCTION

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 dermatologic and ophthalmic disorders and make appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met four times during the reporting period in Bethesda and Gaithersburg, Maryland. The dates of those meetings were:

November 4-5, 1999
November 17, 1999
June 29-30, 2000
September 18-19, 2000

The meeting of November 4-5, 1999, and June 29-30, 2000, included closed sessions to permit discussion of trade secrets or confidential commercial information.

ACCOMPLISHMENTS

On November 4-5, 1999, the full committee conducted general discussions regarding two new drug applications: Loprox, for the treatment of onychomycosis; and Levulan Kerastick, for the treatment of multiple actinic keratoses of the face and scalp. The committee, the guest experts, and the FDA review personnel, discussed the current state of knowledge of the diseases and current treatment options. The committee recommended that Loprox be approved. The FDA accepted the committee's recommendation. While the

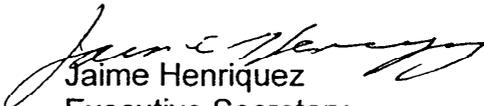
committee consensus on Levulan Kerastick was that there should be a separate patient information handout that would clearly explain the need to cover treated areas adequately, what effects to expect, and appropriate after care. The FDA accepted the committee's recommendation. The meeting of November 5, 1999, included a closed session to permit discussion of trade secret and/or confidential commercial information relevant to pending new drug applications and investigational new drugs.

On November 17, 1999, the Ophthalmic subcommittee discussed a new drug application for Visudyne, for the treatment of age-related macular degeneration in patients with predominantly classic subfoveal choroidal neovascularization. The committee, the guest experts, and the FDA review personnel, discussed the current state of knowledge of the diseases and current treatment options. Overall, the subcommittee's opinion was favorable for the FDA to approve Visudyne. The recommendation was adopted by the FDA and the product was approved in the spring of 2000.

On June 29-30, 2000, the full committee conducted general discussions regarding three new drug applications: 1) Lotrisone, for the treatment of tinea pedis, tinea cruris, and tinea corporis; 2) Dermex, for the treatment of actinic keratosis basal cell carcinoma, and squamous cell carcinoma; and 3) Miconazole Nitrate, for the treatment of diaper dermatitis. The committee, the guest experts, and the FDA review personnel, discussed the current state of knowledge of the diseases and current treatment options. 1) One of the questions that the FDA asked concerning Lotrisone was "what would be an appropriate indication for Lotrisone Lotion?" The committee recommended: systematic, inflammatory tinea pedis, tinea cruris, and tinea corporis. The FDA accepted the committee's recommendation. 2) The committee suggested that Dermex Pharmaceutical form a partnership with a company that can conduct a focused study allowing Dermex to move forward. The FDA accepted the committee's recommendation. 3) The committee recommended to support the proposed indication for Miconazole Nitrate. The FDA accepted the committee's recommendation. The meeting of June 29, 2000, included a closed session to permit discussion of trade secret and/or confidential commercial information relevant to pending new drug applications and investigational new drugs.

On September 18-19, 2000, the full committee conducted general discussions regarding the old and new formulation of Accutane. The committee, the guest experts, and the FDA review personnel, discussed the current state of knowledge of the diseases and current treatment options. The committee recommended that Accutane required more risk management than what the manufacturer was presently providing. The FDA accepted the committee's recommendation.

January 25, 2001
Date


Jaime Henriquez
Executive Secretary

DERMATOLOGIC AND OPHTHALMIC DRUGS ADVISORY COMMITTEE

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ANNUAL REPORT
OF THE
MEDICAL DEVICES ADVISORY COMMITTEE

for the period

October 1, 1999 through September 30, 2000

Function

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the FFDC Act envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner of Food and Drugs regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of Food and Drugs on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between the FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The Panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

MEETINGS

The Medical Devices Advisory Committee held 27 meetings during the reporting period in Gaithersburg, Maryland; and Rockville, Maryland.

Below are the dates of all device panel meetings during FY 2000 (10/1/99 to 9/30/00) and UNDERLINED dates represent meetings that had closed sessions:

<u>10/4/99</u>	Obstetrics and Gynecology Devices Panel
<u>10/28/99</u>	Clinical Chemistry and Clinical Toxicology Devices Panel
<u>11/04/99</u>	Orthopaedic and Rehabilitation Devices Panel
<u>11/19/99</u>	Gastroenterology and Urology Devices Panel
<u>12/6-7/99</u>	Clinical Chemistry and Clinical Toxicology Devices Panel
<u>12/13/99</u>	Immunology Devices Panel
<u>12/15/99</u>	Hematology and Pathology Devices Panel
<u>12/16/99</u>	Radiological Devices Panel
<u>01/12/00</u>	General and Plastic Surgery Devices Panel
<u>1/13-14/00</u>	Ophthalmic Devices Panel
<u>1/20-21/00</u>	Microbiology Devices Panel
<u>1/24-25/00</u>	Obstetrics and Gynecology Devices Panel
<u>2/18/00</u>	Orthopaedic and Rehabilitation Devices Panel
<u>3/1-3/00</u>	General and Plastic Surgery Devices Panel
<u>3/17/00</u>	Ophthalmic Devices Panel
<u>3/24/00</u>	Clinical Chemistry and Clinical Toxicology Devices Panel
<u>3/31/00</u>	Neurological Devices Panel
<u>4/4/00</u>	Circulatory System Devices Panel
<u>5/8/00</u>	General and Plastic Surgery Devices Panel
<u>5/11/00</u>	Neurological Devices Panel
<u>5/11-12/00</u>	Ophthalmic Devices Panel
<u>6/19-20/00</u>	Circulatory System Devices Panel
<u>6/19/00</u>	Gastroenterology and Urology Devices Panel
<u>7/20/00</u>	Orthopaedic and Rehabilitation Devices Panel
<u>7/20-21/00</u>	Ear, Nose and Throat Devices Panel
<u>7/27-28/00</u>	Microbiology Devices Panel
<u>9/11/00</u>	Circulatory System Devices Panel

ACCOMPLISHMENTS

See attachments (accomplishments are reported for 13 panels).

CIRCULATORY SYSTEM DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met three times during the reporting period in Gaithersburg, Maryland.

The dates of the meetings were April 4, 2000, June 19 and 20, 2000 and September 11, 2000.

The meeting on June 20, 2000 included a closed session to permit discussion and review of trade secret and/or confidential commercial information. This portion of the meeting was closed to permit discussion of pending and future circulatory system device submissions. In addition, the committee discussed and reviewed trade secret and/or confidential commercial information presented by a sponsor.

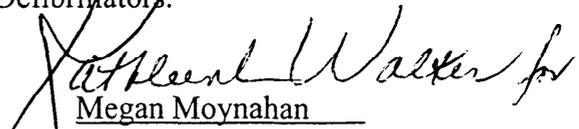
ACCOMPLISHMENTS

During the June 19-20, 2000 meeting, on the first day, a premarket approval application (PMA) for the Cordis IRT System made by Cordis Corporation was recommended for approval with conditions. The conditions were as follows: (1) labeling changes; (2) a multidisciplinary team approach should be required to include physicians and radiation specialists such as an interventional cardiologist, physicist, and oncologist; and (3) postmarketing surveillance would be mandatory, with the FDA standardizing details of the surveillance with the sponsors, but including at a minimum postmarket study of antiplatelet treatment and postapproval data on the premarket cohort for at least five years. This is an intravascular radiation device indicated for the treatment of coronary artery in-stent restenosis.

On the second day, the committee discussed modifications to the guidance document titled, "DRAFT Guidance for Implantable Cardioverter-Defibrillators."

November 13, 2000

Date


Megan Moynahan
Executive Secretary

CIRCULATORY SYSTEM DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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CLINICAL CHEMISTRY and CLINICAL TOXICOLOGY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met three times during the reporting period in Rockville, Maryland and Gaithersburg, Maryland.

The date of those meeting were October 28, 1999, December 6 - 7, 1999 and March 24, 2000.

The meetings on October 28, 1999, and December 7, 1999 included a closed session to permit discussion and review of trade secret and/or confidential commercial information regarding pending and future FDA issues.

ACCOMPLISHMENTS

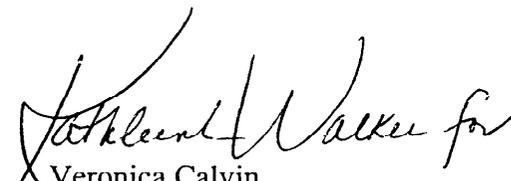
On October 28, 1999, a premarket notification submission (510(k)) was submitted by Polymer Technology Systems, Inc. for the MTM BioScanner T Test Strips. This over-the-counter (OTC) device is intended for measurement of triglycerides from whole blood fingersticks of lay users. The panel recommended that the device was not substantially equivalent because of lack of data and labeling issues.

During the December 6-7, 1999 meeting, on the first day, a PMA presented by Cygnus, Inc. for their GlucoWatch Automatic Glucose Biographer was recommended for approval with the following conditions: (1) an extensive education program should be put into place using model of the prothrombin time home-use meters; and (2) the labeling should be revised according to panel recommendations to be submitted to the FDA. This wrist-worn device is indicated for frequent, automatic and non-invasive monitoring of interstitial glucose levels in adults with diabetes.

On the second day, the panel discussed and made recommendations on general issues regarding OTC devices for measurement of vaginal pH. The discussion included appropriate claims, study designs to support claims, performance expectations, and labeling.

November 13, 2000

Date


Veronica Calvin
Executive Secretary

WORK ADDRESS ROSTER
SORTED BY PANEL/COMMITTEE, FUNCTION, NAME

CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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EAR, NOSE, and THROAT DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met once during the reporting period in Gaithersburg, Maryland.

The date of the meeting was July 20-21, 2000.

The meeting on July 21, 2000, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending issues and applications.

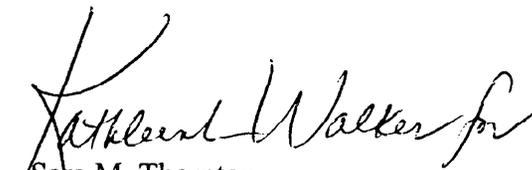
ACCOMPLISHMENTS

During the July 20-21, 2000 meeting, on the first day, a PMA presented by Symphonix, Inc. for the Vibrant Soundbridge System® was recommended for approval with the following conditions: revised intended use statement to read, "The device is indicated for use in adults, 18 years of age and older, who have a moderate to severe sensorineural hearing loss and desire an alternative to an acoustic hearing aid". Prior to receiving the device, it is recommended that an individual have experience with an appropriately fitted acoustical hearing aid. The claims proposed by the sponsor should be modified (numbers 1,2,3,5,6 8 and 9). The information packet should include the statement that the safety and effectiveness of bilateral implants has not been established. The manufacturer should be required to follow patients in a postmarketing surveillance for device extrusion. The possibility of facial nerve paralysis/injury and taste disturbance should be added to page 8 of the patient information packet. The Vibrant Soundbridge consists of two main subsystems: 1) the implant called the Vibrating Ossicular Prosthesis or VORP; and 2) the external amplification system called the Audio

On the second day, the panel discussed another PMA presented by Cochlear Corporation for the Nucleus 24 Auditory Brainstem Implant System. The device is intended to restore useful hearing to individuals 12 years or older with Neurofibromatosis Type II (NF2), who become deaf as a result of surgery to remove bilateral auditory nerve tumors. After deliberations, the panel recommended approval of the PMA subject to the following conditions: (1) the first claim should be revised to indicate that of the 90 patients implanted with the ABI, 82% perceived sound upon stimulation; (2) all claims should be simplified by eliminating fractions of patient numbers and change percentages; (3) the device should be delivered

without the magnet in place, and appropriate modification should be made to the surgeon's manual; (4) a statement should be added that the additional efficacy of bilateral simultaneous implantation has not been studied; (5) information on neurophysical monitoring should be amplified in the surgeon's manual, and recommended training should include more specific guidelines on neurological monitoring and neurological events that may occur during ABI placement; (6) a precaution should state that caution should be used in individuals who have undergone radiotherapy with use of gamma knife because of possible injury to the cochlear nucleus; (7) labeling should indicate that it is strongly recommended that the implantation team should receive training in techniques for appropriate implantation; and (8) the presentation of the efficacy data in the patients information packet should clearly indicate the percentage of patients who did perceive sound.

November 13, 2000
Date


Sara M. Thornton
Executive Secretary (Acting)

**WORK ADDRESS ROSTER
SORTED BY PANEL/COMMITTEE, FUNCTION, NAME**

EAR, NOSE AND THROAT DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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GASTROENTEROLOGY and UROLOGY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met two times during the reporting period in Rockville, Maryland and Gaithersburg, Maryland.

The dates of the meetings were November 19, 1999 and June 19, 2000.

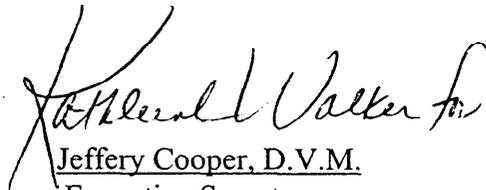
The meeting on November 19, 1999, included a closed session to permit discussion and review of trade secret and/or confidential commercial information regarding present and future FDA issues.

ACCOMPLISHMENTS

On November 19, 1999, a PMA presented by Spectra Sciences, Inc. for the Optical Biopsy System™ (OSB) was recommended for approval subject to the following condition: conduct post-approval study of the OSB during flexible sigmoidoscopy screening procedures in an appropriate number of patients as determined by statistical analysis. As an aid in endoscopic examination, this system utilizes laser energy and autofluorescence to distinguish between hyperplastic and adenomatous polyps (one cm or less) in the colon that may warrant further diagnostic evaluation.

November 13, 2000

Date


Jeffery Cooper, D.V.M.
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**WORK ADDRESS ROSTER
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GENERAL AND PLASTIC SURGERY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met three times during the reporting period in Rockville, Maryland and Gaithersburg, Maryland.

The dates of the meetings were January 12, 2000, March 1-3, 2000 and May 8, 2000.

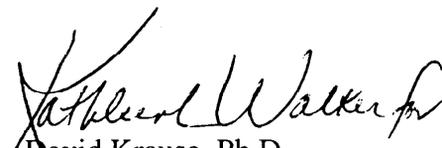
The meeting on January 12, 2000, included a closed session to permit discussion of trade secret and/or confidential information relating to pending issues and applications.

ACCOMPLISHMENTS

On January 12, 2000, a PMA presented by Lifecore Biomedical, Inc. for the Intergel® Adhesion Prevention Barrier Solution was recommended as nonapprovable. The device is indicated as an adjunct to good surgical technique for use as a single use, intraperitoneal instillate for reduction of adhesions following gynecological pelvic laparotomy surgery.

November 13, 2000

Date


David Krause, Ph.D.
Executive Secretary

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HEMATOLOGY and PATHOLOGY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met once during the reporting period in Rockville, Maryland.

The date of the meeting was December 15, 1999.

On December 15, 1999, in a closed session, the committee heard and reviewed trade secret and/or confidential commercial information on a product development protocol (PDP). This portion of the meeting was closed to permit discussion of this information.

ACCOMPLISHMENTS

On December 15, 1999, following the open public session, in a closed session, the panel discussed a product development protocol.

November 13, 2000

Date


Michelle Stuart
Executive Secretary

HEMATOLOGY AND PATHOLOGY DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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IMMUNOLOGY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met one time during the reporting period in Rockville, Maryland.

The date of the meeting was December 13, 1999.

The meeting on December 13, 1999, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending or future device submissions.

ACCOMPLISHMENTS

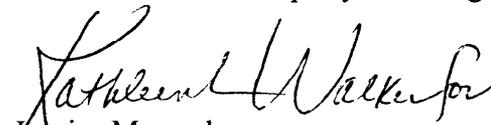
On December 13, 1999 a PMA supplement submitted by Matritech, Inc. for the NMP22 Test Kit was recommended for approval with conditions. The conditions were as follows:

- A change in intended use wording to read, "The Matritech NMP22[®] Test Kit is indicated as an aid in the diagnosis of persons with symptoms or risk factors for transitional cell cancer (TCC) of the bladder (cut-off 7.5 U/mL) in conjunction with and not in lieu of current standard diagnostic procedures, and in the management of patients with transitional cell carcinoma of the bladder after surgical treatment to identify those patients with occult or rapidly recurring TCC (cut-off 10 U/mL)."
- Employ a cut-off of 7.5 U/mL until sufficient calibrators and data are provided to justify lowering the cut-off to the proposed 5 U/mL.

This device was approved in July 1996 as an aid in management of patients with TCC of the bladder after surgical treatment to identify those patients with occult or rapidly recurring TCC.

November 13, 2000

Date


Louise Magruder
Executive Secretary

**WORK ADDRESS ROSTER
SORTED BY PANEL/COMMITTEE, FUNCTION, NAME**

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MICROBIOLOGY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met twice during the reporting period in Rockville, Maryland and Gaithersburg, Maryland.

The dates of the meetings were January 20-21, 2000 and July 27-28, 2000.

The meeting on July 28, 2000, included a closed session to permit discussion and review of trade secret and/or confidential commercial information regarding pending and future device submissions.

ACCOMPLISHMENT

During the July 27-28 meeting, the panel discussed and made recommendations on issues concerning the appropriate types of data and information required to assess the safety and effectiveness of diagnostic tests intended to identify biothreat agents, or to provide evidence of exposure to biothreat agents, when used on different specimen types and under different conditions for use.

At the same meeting, the panel discussed two PMAs sponsored by Roche Molecular System: The first PMA is for the Amplicor™ HCV Test v2.0, a nucleic acid amplification *in vitro* diagnostic qualitative device to detect hepatitis C virus (HCV) ribnucleic acid (RNA) in human serum or plasma. The second PMA is for the Cobas Amplicor™ HCV Test, v2.0 qualitative *in vitro* diagnostic test for the detection of HCV RNA in clinical specimen on the Cobas Amplicor™ Analyzer. The presence of HCV RNA is evidence of current HCV infection in patients presenting with clinical and/or biochemical evidence of liver disease. These assays are not intended for use in screening of blood or blood products for donors. The panel recommended approval with the same conditions for both PMAs.

November 13, 2000
Date


Freddie M. Poole, M.T.
Executive Secretary

MICROBIOLOGY DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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NEUROLOGICAL DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met two times during the reporting period in Rockville, Maryland.

The dates of the meetings were March 31, 2000 and May 11, 2000.

The meeting on March 31, 2000, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending applications.

ACCOMPLISHMENTS

On March 31, 2000, the panel discussed a PMA supplement presented by Medtronic, Inc. for the Activa Deep Brain Stimulator for bilateral implantation to treat Parkinson's disease. The PMA supplement was approved with conditions. The conditions included written instructions for use of the device, extended patient follow-up for 2 to 3 years, and amended indications for the device use. The original PMA was approved in 1997 for unilateral treatment of tremor due to Parkinson's tremors and essential tremors.

November 13, 2000
Date


Jan Scudiero
Executive Secretary

**WORK ADDRESS ROSTER
SORTED BY PANEL/COMMITTEE, FUNCTION, NAME**

NEUROLOGICAL DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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OBSTETRICS and GYNECOLOGY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met two times during the reporting period in Rockville, Maryland and Gaithersburg, Maryland.

The dates of the meetings were October 4, 1999 and January 24-25, 2000.

The meetings on October 4, 1999 and January 25, 2000, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending and future device issues.

ACCOMPLISHMENTS

On October 4, 1999, the panel discussed issues for new barrier contraceptive devices, such as premarket study design, prescription versus OTC availability, and premarket versus postmarket studies. The discussion included what the appropriate controls should be, study size, length of follow-up to determine pregnancy rates, safety evaluations, labeling for the physician and patient, and whether these devices should be made available through prescription only or OTC. The Obstetrics and Gynecology Devices Branch will consider the panel's suggestion and recommendations as they develop guidance for new female barrier contraceptive devices. Following the barrier contraceptive discussion, the panels discussed clinical study requirements for new nonextirpative methods of treating uterine fibroids. The discussion included the appropriateness of a randomized controlled study design, the appropriate study endpoints, length of follow-up, quality of life measures, inclusion/exclusion criteria, labeling with respect to pregnancy following a procedure, and postmarket studies. The panel's recommendations will be considered as the Obstetrics and Gynecology Devices Branch develops guidance for the development of devices used to treat uterine fibroids.

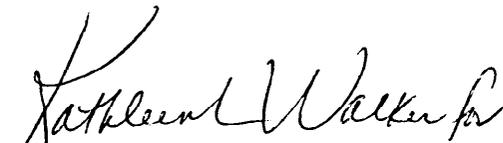
On January 24-25, 2000, during the first day, the panel discussed Mallinckrodt, Inc.'s PMA for Nellcor N-400 Fetal Oxygen Saturation Monitoring System, a-first-of-a kind intrapartum fetal pulse oximeter. This device continuously monitors fetal oxygen saturation (FsPO₂) and is indicated for use as an adjunct to fetal heart rate (FHR) monitoring to better assess fetal oxygen status in the presence of a non-reassuring heart rate pattern during labor and delivery. Following the deliberations, the panel recommended approval of the PMA with conditions.

On the second day, the Panel discussed a draft guidance document on adhesion barrier products intended for use in pelvic and/or abdominal surgery. The panel provided the following recommendations to FDA regarding:

- Use of surrogate endpoints (e.g. adhesion incidence, extent, severity, scoring systems for adhesions) versus clinical endpoints (e.g. infertility, chronic pelvic pain, small bowel obstruction);
- premarket versus postmarket study of clinical endpoints;
- extrapolation of data for a) de novo to reformed adhesions, b) gynecologic models to general surgery; and c) site-specific application to alternative sites in the abdominopelvic cavity; appropriate methods for masking a trial;
- laparoscopy versus laparotomy indications; and
- data on the potential of an adhesion barrier product to enhance infection

November 13, 2000

Date



Elisa Harvey, Ph.D., D.V.M.

Executive Secretary

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SORTED BY PANEL/COMMITTEE, FUNCTION, NAME

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OPHTHALMIC DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met three times during the reporting period in Rockville, Maryland and Gaithersburg, Maryland.

The dates of the meetings were January 13-14, 2000; March 17, 2000; and May 11-12, 2000.

The meeting on January 13, 2000, included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending issues and applications.

ACCOMPLISHMENTS

On January 13-14, 2000, during the first day, a PMA sponsored by Sun Rise Technologies International, Inc. for the Hyperion LTK System was recommended for approval with conditions. The device is indicated for the temporary reduction of hyperopic refractive error. On the second day, the panelists recommended that artificial eye care products intended for the lubricating and/or cleaning of artificial eyes be reclassified into class II. On the same day, the panel recommended to the FDA that implantable eyelid weights intended for the management of incomplete eyelid closure be classified into class II. In addition, the panel voted that External Eyelid Weight intended for the management of incomplete eyelid closure be classified into class II.

November 13, 2000
Date


Sara M. Thornton
Executive Secretary

OPHTHALMIC DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE

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ORTHOPAEDIC and REHABILITATION DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The panel met three times during the reporting period in Rockville, Maryland and Gaithersburg, Maryland.

The dates of the meetings were November 4, 1999, February 18, 2000 and July 20, 2000.

The meeting on November 4, 1999, included a closed session to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future device issues. On February 18, 2000, a closed committee deliberation was held during which the panel discussed and made recommendations on a product development protocol (PDP). This portion of the meeting was closed to permit discussion of this information.

ACCOMPLISHMENTS

On November 4, 1999, the panel recommended to the FDA that class III constrained total hip arthroplasty devices be classified into class II 510(k) with the use of special controls. At the same meeting, the panel provided comments to the FDA regarding the development of computer controlled surgical systems designed for use in orthopaedic procedures. The discussion included the intended use, clinical end points, and the use of surrogate endpoints.

On February 18, 2000, during the open public session, FDA staff presented an update to the committee regarding the status of submissions from past panel meetings. Following the open public session, in a closed session, the panel discussed a PDP. This discussion was conducted in a closed session because the panel heard and reviewed trade secret and/or confidential commercial information as part of the PDP.

November 13, 2000

Date


Hany Demian
Executive Secretary

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ORTHOPAEDIC AND REHABILITATION DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE, FDA

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Annual Report
Of the
Science Advisory Board to the National Center for Toxicological research
For the period
October 1, 1999 through September 30, 2000

FUNCTION

The Board advises the Director, NCTR, in establishing, implementing and evaluating the research programs that assist the Commissioner of Food and Drugs in fulfilling his/her regulatory responsibilities. The Board provides an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met one time during the reporting period in Jefferson, AR.

The date of the meeting was June 5-6, 2000.

The meeting on June 6, 2000 included a closed session to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy. (5 U.S.C. 552b (c) (6)). The Board discussed qualifications and performance of individuals associated with the research programs at the Center that had undergone review.

ACCOMPLISHMENTS

The Board received updated reports from the Biochemical Toxicology, Genetic Toxicology, and the Molecular Epidemiology program Directors. They addressed the issues raised and actions taken on the recommendations made in the program review reports. They also were presented with draft reports from the Chair's of the site visits on the Center's Endocrine Disrupters Knowledge Base Project and the Microbiology Program. The Board unanimously approved both of the draft reports.

Date: 11/16/00


Ronald F. Coene, P.E.
Executive Secretary

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