

- AR-10 Smoke-Free Workplace Requirements.
- AR-11 Healthy People 2010.
- AR-12 Lobbying Restrictions.
- AR-14 Accounting System Requirements.
- AR-15 Proof of Non-Profit Status.
- AR-21 Small, Minority, and Women-Owned Business.
- AR-22 Research Integrity.
- AR-23 States and Faith-Based Organizations.
- AR-24 Health Insurance Portability and Accountability Act Requirements.
- AR-25 Release and Sharing of Data.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgofunding/ARs.htm>.

VI.3. Reporting

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, (use form PHS 2590, OMB Number 0925-0001, rev. 5/2001 as posted on the CDC website) no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:
 - a. Current Budget Period Activities Objectives.
 - b. Current Budget Period Financial Progress.
 - c. New Budget Period Program Proposed Activity Objectives.
 - d. Budget.
 - e. Additional Requested Information.
 - f. Measures of Effectiveness.
2. Financial status report and annual progress report no more than 90 days after the end of the budget period.
3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management Specialist listed in the "Agency Contacts" section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For scientific/research issues, contact: Brenda Colley Gilbert, Extramural Project Officer, NCCDPHP/Deputy Associate Director for Extramural Research (DADER), 4770 Buford Highway, NE., Mail Stop K20, Atlanta, GA 30341-3717, Telephone: 770-488-6295, E-mail: BColleyGilbert@CDC.GOV.

For questions about peer review, contact: Brenda Colley Gilbert, Scientific Review Administrator, 4770 Buford Highway, NE., Mail Stop K20, Atlanta, GA 30341-3717, Telephone: 770-488-6295, E-mail: BColleyGilbert@CDC.GOV.

For financial, grants management, or budget assistance, contact: Tracey Sims, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2739, E-mail: Tsims3@cdc.gov.

VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: <http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements."

Dated: August 17, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04-19310 Filed 8-23-04; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003P-0548]

Determination That DECADRON-LA (Dexamethasone Acetate Injection), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that DECADRON-LA (dexamethasone acetate injection), 8 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. As a result of this determination, FDA may approve abbreviated new drug applications (ANDAs) for dexamethasone acetate injection, 8 mg/mL.

FOR FURTHER INFORMATION CONTACT: Howard P. Muller, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301-594-2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which

authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is typically a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

Under § 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. If the agency determines that a listed drug was withdrawn for reasons of safety or effectiveness, the drug must be removed from the list of approved drug products, and ANDAs referencing that drug may not be approved (§ 314.162).

DECADRON-LA (dexamethasone acetate injection), 8 mg/mL, is the subject of approved NDA 16-675 held by Merck. In a letter to the agency dated June 25, 2002, Merck requested that NDA 16-675 be withdrawn because the drug is no longer marketed. Merck noted that the NDA was not withdrawn because of safety reasons. On December 5, 2003, Gray Cary submitted a citizen petition (Docket No. 2003P-0548/CP1) to FDA under 21 CFR 10.30 requesting that the agency determine whether DECADRON-LA (dexamethasone acetate injection), 8 mg/mL, NDA 16-675, was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that DECADRON-LA (dexamethasone acetate injection), 8 mg/mL, was not withdrawn from sale for reasons of

safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports associated with this drug and has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously, DECADRON-LA (dexamethasone acetate injection), 8 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DECADRON-LA (dexamethasone acetate injection), 8 mg/mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to DECADRON-LA (dexamethasone acetate injection), 8 mg/mL, may be approved by the agency.

Dated: August 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-19287 Filed 8-23-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

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

Date and Time: The meeting will be held on September 21, 2004, from 9 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Geretta Wood, Center for Devices and Radiological Health (HFZ-450), Food and Drug

Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8320, ext. 143, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations regarding clinical trial design in the evaluation of cardiopulmonary resuscitation enhancing devices/therapies for cardiac arrest patients. Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 7, 2004. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 7, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301-594-1283, ext. 113, at least 7 days in advance of the meeting.

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

Dated: August 17, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04-19288 Filed 8-23-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

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

Pichia pastoris Cloning Systems for Expressing and Secreting Proteins of Interest

James Hartley (NCI/SAIC-Frederick).DHHS Reference No. E-305-2004/0—Research Tool.

Licensing Contact: Michael Shmilovich; (301) 435-5019; shmilovm@mail.nih.gov.

Biological materials of a *Pichia pastoris* cloning and expression system are available for licensing for internal use. The system provides a vector for transgenically expressing proteins that are secreted through signal peptide mediation (e.g., the α mating factor signal peptide). This expression system utilizes the Gateway® cloning platform from Invitrogen without interference from the Gateway® *attB1* sequence. The α mating factor signal peptide encoding sequence includes an *attB1* insertion at an XhoI site upstream from some gene of interest (e.g., human interferon Hyb3). The *attB1* site does not alter the secretion or processing of the signal peptide.