both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 28, 2005.

Alvin Hall,

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

[FR Doc. 05–13131 Filed 7–1–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Prospective Grant of Exclusive License: Diagnostics of Fungal Infections; Correction

In the notice document appearing on page 33905 in the **Federal Register** issued on Friday, June 10, 2005, Vol. 70, No. 111, make the following correction:

On page 33905 under Centers for Disease Control and Prevention, change the title ''Prospective Grant of Exclusive License: Diagnostics of Fungal Infections'' to ''Prospective Grant of Exclusive License: System and Methods for Aerosolized Delivery of Vaccines'' (remove previous title ''Diagnostics of Fungal Infections'').

All other information in the document remains unchanged.

Dated: June 24, 2005.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

[FR Doc. 05–13132 Filed 7–1–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cellular, Tissue and Gene Therapies Advisory Committee (formerly Biological Response Modifiers Advisory Committee); Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

Name of Committee: Cellular, Tissue and Gene Therapies 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, via teleconference, on July 29, 2005, from 12:30 p.m. to 2:30 p.m.

Location: National Institutes of Health, Bldg. 29B, conference room C, 8800 Rockville Pike, Rockville, MD. This meeting will be held by teleconference. The public is welcome to attend the meeting at the previously mentioned location. A speakerphone will be provided at the specified location for public participation in the meeting.

Contact Person: Gail Dapolito, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512389. Please call the Information Line for up-to-date information on this meeting.

Agenda: In open session, the committee will hear brief opening remarks and allow time for public participation and comments related to individual FDA research programs during the open public hearing. The committee will not hear presentations or discuss individual research programs in the open session (see *Closed Committee Deliberations* below).

Procedure: On July 29, 2005, from 12:30 p.m. to 1:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 21, 2005. Oral presentations from the public will be scheduled between approximately 12:30 p.m. to 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 21, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On July 29, 2005, from approximately 1:30 p.m. to 2:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss a review of individual FDA research programs.

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 Gail Dapolito 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: June 23, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–13122 Filed 7–1–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0333]

Draft Guidance; Emergency Use Authorization of Medical Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft guidance entitled ''Emergency Use Authorization of Medical Products.'' The draft guidance explains FDA's policies for authorizing the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency. The draft guidance is not final and is not in effect at this time. FDA also is announcing an opportunity for public comment on the proposed collection of information related to emergency use authorizations by the agency.

DATES: Submit written or electronic comments on the draft guidance and the proposed collection of information by September 6, 2005.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Counterterrorism Policy and Planning (HF–29), Food and Drug Administration, 5600 Fishers Lane, rm. 14C–26, Rockville, MD 20857. Send a self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–827–5671. Submit written comments on the draft guidance and the proposed collection of information to the Division of Dockets

Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. All comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

For information on the draft guidance: Charlotte Christin, Office of Counterterrorism Policy and Planning (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

For information on the proposed collection of information: JonnaLynn Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft guidance for industry, government agencies, and FDA staff entitled ''Emergency Use Authorization of Medical Products.'' This draft guidance describes the agency's general recommendations and procedures for issuance of emergency use authorizations (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bbb–3), which was amended by the Project BioShield Act of 2004 (Public Law 108–276).

Section 564 of the act provides for authorization of ''emergency use'' of a medical product, after a declaration of emergency justifying an authorization is issued by the Secretary of Health and Human Services (the Secretary) based on one of the following grounds: A determination by the Secretary of Homeland Security that there is an actual or potential ''domestic emergency;'' a determination by the Secretary of Defense that there is an actual or potential ''military emergency;'' or a determination by the Secretary that there is a public health emergency under section 319 of the Public Health Service Act that affects or has the significant potential to affect national security. The Commissioner of FDA (the Commissioner) may issue an EUA for an unapproved drug, device, or biologic, or an unapproved use of an approved drug, device, or biologic, during a declared emergency.

This draft guidance, when finalized, may be supplemented by guidance from the FDA Centers that provides additional detail on these recommendations and procedures.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Reporting and Recordkeeping for Emergency Use Authorization of Medical Products

The act permits the Commissioner to authorize the use of unapproved medical products or unapproved uses of approved medical products during an emergency declared under section 564 of the act. The data to support issuance of an EUA must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb–3(c)). Although the exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency and the nature of the candidate product, FDA recommends that a request for consideration for an EUA include scientific evidence evaluating the product's safety and effectiveness, including the adverse event profile for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

Under section 564, the Commissioner may establish conditions on the approval of an EUA. Section 564(e) requires the Commissioner (to the extent practicable given the circumstances of the emergency) to establish certain conditions on an authorization that the Commissioner finds necessary or appropriate to protect the public health and permits the Commissioner to establish other conditions that he finds necessary or appropriate to protect the public health. Conditions authorized by section 564(e) of the act include, for example: Requirements for information dissemination to health care providers or authorized dispensers and product recipients; adverse event monitoring and reporting; data collection and analysis; recordkeeping and records access; restrictions on product advertising, distribution, and administration; and limitations on good manufacturing practices requirements. Some conditions, the statute specifies, are mandatory to the extent practicable for authorizations of unapproved products and discretionary for authorizations of unapproved uses of approved products. Moreover, some conditions may apply to manufacturers of an EUA product, while other conditions may apply to any person who carries out any activity for which the authorization is issued. Section 564 of the act also gives the Commissioner authority to establish other conditions on an authorization that the Commissioner finds to be necessary or appropriate to protect the public health.

For purposes of estimating the burden of reporting, FDA has established six categories of respondents which include: (1) Those who file a Request for Consideration for an EUA after a determination of actual or potential emergency and, in lieu of submitting the data, provide reference to a pending or approved application; (2) those who file a Request for Consideration for an EUA and the data after a determination of actual or potential emergency, without reference to a pending or approved application; (3) those who submit data to FDA on a candidate EUA product, which is subject to a pending or approved application, prior to a

determination of actual or potential emergency; (4) those who submit data to FDA prior to a determination of actual or potential emergency about a candidate EUA product for which there is no pending or approved application; (5) manufacturers of an unapproved EUA product who must report to FDA regarding such activity; and (6) State and local public health officials who carry out an activity related to an unapproved EUA product (e.g., administering the product to civilians) and who must report to FDA regarding such activity.

For purposes of estimating the burden of recordkeeping, FDA has calculated the anticipated burden on manufacturers of unapproved products authorized for emergency use. The agency anticipates that the Federal Government will perform some of the additional recordkeeping necessary for unapproved products (e.g., related to the administration of unapproved EUA products to military personnel). FDA also anticipates that some State and local public health officials may be required to perform additional recordkeeping (e.g., related to the administration of unapproved EUA products to civilians) and calculated a recordkeeping burden for those activities.

No burden was attributed to reporting or recordkeeping for unapproved uses of approved products, since those products already are subject to approved collections of information (adverse experience reporting for biological products is approved under OMB control number 0910–0308 through May 31, 2005; adverse drug experience reporting is approved under OMB control number 0910–0230 through September 30, 2005; and investigational new drug applications (IND) regulations are approved under OMB control number 0910–0014 through January 31, 2006) and any additional burden imposed by this proposed collection would be minimal. Thus, FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Request for Consideration; Pending application on file	1	1	1	15	15
Request for Consideration; No application pending	1	1	1	50	50
Pre-emergency submissions; Pending application on file	10	1	10	20	200
Pre-emergency submissions; No application pending	3	1	3	75	225
Manufacturers of an unapproved EUA product	3	4	12	2	24
State and local public health officials; Unapproved EUA product	30	4	120	2	240
Total					754

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Manufacturers of an unapproved EUA product	3	4	12	25	300
State and local public health officials; Unapproved EUA product	30	4	120	3	360
Total					660

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The annual burden estimate for this information collection is 1,414 hours. The estimated reporting burden for this collection is 754 hours and the estimated recordkeeping burden is 660 hours.

III. Significance of Guidance

This draft guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on emergency use authorizations of medical products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any

mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain copies of this draft guidance at *http://www.fda.gov/opacom/morechoices/industry/guidedc.htm*.

Dated: June 27, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–13121 Filed 7–01–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: May 2005

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of May 2005, the HHS Office of Inspector General imposed exclusions in cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care Programs. In addition, no program payment is made to any business or facility, *e.g.,* a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject name, address	Effective date
Program-Related Convictions	
Adoff, Arnold Valhalla, NY	6/20/2005
Agett, Deborah Kingsport, TN	6/20/2005
Albanese, Anthony Brooklyn, NY	3/29/2005
Albarracin, Carlos Palmdale, CA	6/20/2005
Aloma, Filomena Miami, FL	6/20/2005
Alvarez, Jose Miami, FL	6/20/2005
Arenales, Anna Hialeah, FL	6/20/2005
ARS Professional Pharmacy, LTD Monsey, NY	6/20/2005
Barreda, Celina Miami, FL	6/20/2005
Beauchene, Tracey Aberdeen, WA	6/20/2005
Birotech Corporation Tampa, FL	6/20/2005
Bonett, Olga Camden, NJ	6/20/2005
Canning, Joyce Sanford, ME	6/20/2005
Chancy, Luke Kelso, WA	6/20/2005
Curbelo, Sue Glendale, CA	6/20/2005
Dean, Nancy Danbury, CT	6/20/2005
Depaula, Grisel Miami, FL	6/20/2005
Dubois, Marylin Paradis, LA	6/20/2005
Espinosa, Sara Miami, FL	6/20/2005
Gibbs, Debra Fayetteville, NC	6/20/2005
Gilley, Margaret Ellsworth, ME	6/20/2005
Gladkovister, Petr Shorewood, WI	6/20/2005
Goode, Constance Essex Junction, VT	6/20/2005
Hill, Stella Sacramento, CA	6/20/2005
Hines, Shelia Enfield, NC	6/20/2005
Hoover, Ronald Manchester, KY	6/20/2005
Howze, Andreco Great Falls, SC	6/20/2005
Ince, Karen Hollis, NY	6/20/2005
Joyner, Connie Clinton, NC	6/20/2005
Karapetyan, Margarita Los Angeles, CA	6/20/2005
Katherine, Scott Minersville, PA	6/20/2005
Kaufman, Brian Honeoye Falls, NY	6/20/2005
Leafa, Tina Seatac, WA	6/20/2005
Lennon, Dionne Wadesboro, NC	6/20/2005
Loveall, Amy Fulton, NY	6/20/2005
McCloskey, Debra Schenectady, NY	6/20/2005
Mora, Zoraida Miami, FL	6/20/2005
Morales-Montalvo, Carlos San German, PR	6/20/2005
Nemirovskaya, Viktoria Cedarburg, WI	6/20/2005
Nsekpong, Michael Seagoville, TX	6/20/2005
Pederson, Randi Fargo, ND	6/20/2005
Porter, Kevin Shelby, NC	6/20/2005
Purcell, Donald Napa, CA	6/20/2005
Rascoe, Jessica Windsor, NC	6/20/2005
Reardon, Gina Cumming, GA	6/20/2005
Reusche, Jane Fort Myers, FL	6/20/2005
Ricketts, Donna Hendersonville, TN	6/20/2005
Rivera-Iglesias, Jorge Cabo Rojo, PR	6/20/2005
Rivera-Iglesias, Wilson Cabo Rojo, PR	6/20/2005
Rodriguez-Sorrentini, Eric Cabo Rojo, PR	6/20/2005
Rodriquez-Sorrentini, Noel Cabo Rojo, PR	6/20/2005
Senquiz, Luz Philadelphia, PA	6/20/2005
Showell, Stephanie Georgetown, DE	6/20/2005
Stanley A Gorgol, D P M, Inc, Corp Salem, NH	6/20/2005
Symkowski, Yanina Waukesha, WI	6/20/2005
Taft, William Cornelius, NC	6/20/2005
Tatman, April Thornville, OH	6/20/2005
Taylor, Patricia Wiggins, MS	6/20/2005
Thomas-Hicks, Michelle Taylor, MI	6/20/2005
Thurn, Anita Scott, LA	6/20/2005
Thurn, Melvin Breaux Bridge, LA	6/20/2005
Uko, Ekong Chatsworth, CA	6/20/2005
Underwood, Paul Charlotte, NC	6/20/2005
Urbano-Jane, Gloria Miami, FL	6/20/2005
Vann, Hoeuth Long Beach, CA	6/20/2005
Warren, Constanza Altamonte Springs, FL	6/20/2005
Weir, Burnadett Hollis, NY	6/20/2005
Williams, Taranika Minneapolis, MN	6/20/2005
Wright, Carrie Eden, NY	6/20/2005
Felony Conviction for Health Care Fraud	
Amato, Nicola Flanders, NJ	6/20/2005
Bass, Theresa Imperial, MO	6/20/2005
Cazel, Phillip Newcastle, CA	6/20/2005
Colon, Margaret E Falmouth, MA	6/20/2005
Crowder, Linda Lancaster, CA	6/20/2005
Duhon, Paula	6/20/2005