Official. If applications are found to be not responsive to this announcement, they will be returned to the applicant without further consideration.

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts in the subject field of the specific application.

Responsive applications will also be subject to a second level of review by a National Advisory Council for concurrence with the recommendations made by the first level reviewers. Final funding decisions will be made by the Commissioner of Food and Drugs or his designee.

B. Review Criteria

Applicants must clearly state in their application for which of the requested projects they are applying. All applications will be evaluated by program and grants management staff for responsiveness. Applications will be reviewed and ranked within each project category. There is no assurance that awards will be made in each of the five project categories. If a project category is funded, funding will start with the highest ranked application within that project category, and any additional awards within that project category will be made based on the next highest ranked application. All questions of a technical or scientific nature should be directed to the CFSAN program staff (See the **FOR FURTHER INFORMATION CONTACT** section of this document for addresses.), and all questions of an administrative or financial nature should be directed to Maura Stephanos of the Grants Management Staff (address above).

All applications will be reviewed and scored on the following criteria:

1. Soundness of the scientific rationale for the proposed study and appropriateness of the study design and its ability to address all of the objectives of the RFA;

2. Availability and adequacy of laboratory facilities, equipment, and support services, e.g., bio-statistics computational support, databases, etc.;

3. Research experience, training, and competence of the principal investigator and support staff; and

4. Whether the proposed study is within the budget guidelines and proposed costs have been adequately justified and fully documented.

VII. Submission Requirements

The original and two copies of the completed Grant Application Form PHS 398 (Rev. 4/98 or Rev. 5/01) or the original and two copies of PHS 5161–1 (Rev. 7/00) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Maura Stephanos (address above). State and local governments may choose to use the PHS 398 application form in lieu of PHS 5161–1. The application receipt date is May 30, 2002. No supplemental or addendum material will be accepted after the receipt date. The outside of the mailing package and item 2 of the application face page should be labeled: ''Response to RFA FDA CFSAN–02–1, (insert Project #1, 2, 3, 4, or 5).''

VIII. Method of Application

A. Submission Instructions

Applications will be accepted during normal business hours, from 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date. Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. (Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.) Do not send applications to the Center for Scientific Research (CSR), NIH. Any application that is sent to NIH, and is then forwarded to FDA and not received in time for orderly processing will be deemed not responsive and returned to the applicant. Applications must be submitted via mail or hand delivery as stated above. FDA is unable to receive applications electronically. Applicants are advised that FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by NIH on its applications.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 4/98 or Rev. 5/01) or PHS 5161–1 (Rev. 7/00). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt dates and the mailing label address.

The face page of the application should reflect the request for applications number, RFA–FDA–CFSAN–02–1, (insert Project #1, 2, 3, 4, or 5).

Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001. The requirements requested on Form PHS 5161–1 were approved and assigned OMB control number 0348–0043.

C. Legend

Unless disclosure is required by FOIA as amended (5 U.S.C. 552) as determined by the freedom of information officials of DHHS or by a court, data contained in the portions of this application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: March 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–9098 Filed 4–12–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0115]

Risk Management of Prescription Drugs; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) is announcing a public hearing on the agency's approach to risk management of prescription drugs. In May 1999, FDA published ''Managing the Risks From Medical Product Use,'' which laid a framework for the agency's efforts to reduce the risks involved with medical product use. The public hearing announced in this notice is part of the agency's ongoing efforts to improve CDER's risk communication and to develop new and effective risk management tools. The purpose of the

hearing is to obtain public input on improving risk management of prescription drugs; identify stakeholders for further collaboration on development and implementation of risk management tools; obtain greater understanding of the strengths and weaknesses of existing risk management tools, which should help guide improvements or creation of new tools; and obtain input on strategies to assess the effectiveness of tools used for risk management of prescription drugs.

DATES: The public hearing will be held on Wednesday, May 22, 2002, from 8 a.m. to 4:30 p.m. Submit written or electronic notices of participation and comments for consideration at the hearing by April 23, 2002. Written or electronic comments will be accepted after the hearing until June 21, 2002.

ADDRESSES: The public hearing will be held at the National Transportation Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594 (Phone: 202–314–6421; Metro: L'Enfant Plaza Station on the green, yellow, blue, and orange lines). Submit written or electronic notices of participation and comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; email: *FDADockets@oc.fda.gov*; or on the Internet at *http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm*. Transcripts of the hearing will be available for review at the Dockets Management Branch (address above) and on the Internet at *http://www.fda.gov/ohrms/dockets*.

FOR FURTHER INFORMATION CONTACT: Christine Bechtel, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5458, *bechtelc@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA approves medical products when the agency determines that the benefits of using a product outweigh the risks for the intended population and use. The product must be labeled with adequate information on its risks and benefits. The labeling must also provide sufficient information to ensure the product is safely used to produce the stated effect. Labeling is given considerable emphasis because it is the primary tool the agency uses to communicate risk and benefit to the public. Once the medical product is marketed, however, ensuring safety becomes a complicated responsibility shared by many parties, including health care providers, manufacturers, patients, and others. New information on safety that needs dissemination often arises postmarketing. Occasionally, a product's safety and efficacy profile changes, resulting in the need for safety intervention beyond labeling (*e.g.*, to protect the public or a population subgroup from increased risks). When such situations arise, effective risk management tools are needed.

Many critics have expressed concern that the current risk management system for drugs is inadequate. The number of drugs available on the market is increasing along with their complexity. The potential for interactions among various treatments is also growing and is beyond the ability of many busy physicians to track. In addition, changes in the health care delivery system, advertising, third-party payer programs, and other forces are challenging the current risk management system. Recent studies of the effectiveness of FDA's traditional risk communication tools (*i.e.*, the ''dear health care practitioner letter'' and the black box warning in product labeling) have demonstrated that these tools have limited effect in changing the behavior of health care providers with regard to prescribing and monitoring patients' health (Refs. 1, 2, and 3).

II. Scope of the Hearing

FDA is interested in obtaining public comment on the following issues:

A. Risk Communication

- What improvements are needed to enhance communication about safety issues for drugs?
- What improvements are needed to communicate information about the efficacy of drugs?
- What are the strengths and weaknesses of the agency's current risk labeling approach?
- How can communication with health care practitioners become more effective (*e.g.*, improve the ''dear health care practitioner letter'' and other current communication strategies)?
- What other steps should FDA be taking to communicate risks and benefits?

B. Tools for Risk Management

- What methods should FDA be using to manage risk?
- What new tools can be created to better address specific drug risks?
- What are the advantages and disadvantages of restricted marketing as a risk management tool?
- What risk interventions can FDA initiate for pharmacists, physicians, patients, and drug manufacturers?

C. Evaluation of Risk Management Strategies and Interventions

- What risk management interventions should be studied for effectiveness?
- What criteria should be used to judge if a risk management intervention is effective?

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs (the Commissioner) is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Commissioner or his designee. The presiding officer will be accompanied by a panel of FDA employees with relevant expertise.

Persons who wish to participate in the part 15 hearing must file a written or electronic notice of participation with the Dockets Management Branch (*see* **ADDRESSES**) before April 23, 2002. To ensure timely handling, any outer envelope should be clearly marked with the docket number listed at the head of this notice along with the statement ''Risk Management of Prescription Drugs Hearing.'' Groups should submit two written copies. The notice of participation should contain the person's name; address; telephone number; affiliation, if any; the sponsor of the presentation (*e.g.*, the organization paying travel expenses or fees), if any; a brief summary of the presentation; and approximate amount of time requested for the presentation. The agency requests that interested persons and groups having similar interests consolidate their comments and present them through a single representative. After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by telephone of the time allotted to the person and the approximate time the person's oral presentation is scheduled to begin. If time permits, FDA may allow interested persons attending the hearing who did not submit a written or electronic notice of participation in advance to make an oral presentation at the conclusion of the hearing. The hearing schedule will be available at the hearing. After the hearing, the hearing schedule will be placed on file in the Dockets Management Branch under the docket number listed at the head of this notice.

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt

the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). The transcript of the hearing will be available on the Internet at *http://www.fda.gov/ohrms/dockets*, and orders for copies of the transcript can be placed at the meeting or through the Dockets Management Branch (*see* **ADDRESSES**).

Any handicapped persons requiring special accommodations to attend the hearing should direct those needs to the contact person (*see* **FOR FURTHER INFORMATION CONTACT**).

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

IV. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic notices of participation and comments for consideration at the hearing by April 23, 2002. To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing until June 21, 2002. Persons who wish to provide additional materials for consideration should file these materials with the Dockets Management Branch (*see* **ADDRESSES**) by June 21, 2002. Two copies of any written comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number at the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Jones, J. K., D. Fife, S. Curkendall et al., ''Coprescribing and Codispensing of Cisapride and Contraindicated Drugs,'' *Journal of the American Medical Association*, 286:1607–1609, 2001.

2. Graham, D. J., C. R. Drinkhard, D. Shatin et al., ''Liver Enzyme Monitoring in Patients Treated With Troglitazone,'' *Journal of the American Medical Association*, 286:831–833, 2001.

3. Smalley, W., D. Shatin, D. K. Wysowski et al., ''Contraindicated Use of Cisapride: Impact of Food and Drug Administration Regulatory Action,'' *Journal of the American Medical Association*, 284: 3036–3039, 2002.

Dated: April 8, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–9096 Filed 4–12–02; 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, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies 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.

Methods for Using Modulators of Extracellular Adenosine or an Adenosine Receptor to Enhance Immune Response and Inflammation

Michail V. Sitkovsky, Akio Ohta (NIAID),
DHHS Reference No. E–051–02/1 filed 19 Dec 2001,
Licensing Contact: Cristina Thalhammer-Reyero; 301/496–7736 ext. 263; e-mail: *thalhamc@od.nih.gov.*

Local inflammation processes are crucially important in the host defense against pathogens and for successful immunization because pro-inflammatory cytokines are necessary for initiation and propagation of an immune response. However, normal inflammatory responses are eventually terminated by physiological termination mechanisms, thereby limiting the strength and duration of immune responses, especially to weak antigens. The inventors have shown that adenosine receptors play a critical and non-redundant role in down-regulation of inflammation in vivo by acting as the physiological termination mechanism that can limit the immune response. The adenosine A2a and A3a receptors have been identified as playing a critical role in down-regulation of the immune response during inflammation.

This invention claims methods for inhibiting signaling through the adenosine receptor to prolong and intensify the immune response. The method involves administering either an adenosine-degrading drug or an adenosine receptor agonist. Also claimed in the invention is use of adenosine receptor agonists or adenosine-degrading drugs as vaccine adjuvants and methods for accomplishing targeted tissue damage such as for tumor destruction. This invention is further described in Ohta A et al., ''Role of G-protein-coupled adenosine receptors in downregulation of inflammation and protection from tissue damage,'' Nature 2001 Dec 20–27;414(6866):916–20.

Novel Spore Wall Proteins and Genes From Microsporidia

J. Russell Hayman, John T. Conrad, Theodore Nash (NIAID),
DHHS Reference No. E–125–01/0 filed 04 Dec 2001,
Licensing Contact: Peter Soukas; 301/496–7056 ext. 268; e-mail: *soukasp@od.nih.gov.*

Microsporidia are obligate intracellular organisms that infect a wide variety of animals ranging from insects and fish to mammals, including humans. Of over 1000 microsporidial species identified, at least thirteen are known to infect humans. The species most commonly identified in humans are members of the families Encephalitozoonidae and Enterocytozoonidae. In humans, microsporidiosis is most often found in HIV/AIDS patients and commonly results in severe diarrhea and wasting. However, microsporidiosis also occurs in immunocompetent individuals and common farm animals. The disease is