NOTIFICATION PROCEDURE:

For the purpose of access, the subject individual should write to the system manager who will require the system name, address, age, gender type, and, for verification purposes, the subject individual's name (woman's maiden name, if applicable).

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 05–19676 Filed 9–30–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration on Children, Youth, and Families; Notice of Award of Non-Competitive Grant

AGENCY: Administration on Children, Youth and Families, ACF, HHS.

ACTION: Award announcement.

SUMMARY: The Administration on Children, Youth and Families herein announces an urgent grant award to the National Association of Child Care Resource and Referral Agencies (NACCRRA) to provide technical assistance to reestablish the operations of the resource and referral agencies in Mississippi and Louisiana whose operations have been disrupted by Hurricane Katrina. This grant will help to re-establish child care referral services so that families along the Gulf Coast can find child care. This grant will also support local and Statewide inventories of child care need and availability.

The amount of the proposed grant to NACCRRA is $99,500 in FY 2005 child care funds. The duration of the grant is 12 months.

Statutory Authority: This award will be made pursuant to the Child Care and Development Block Grant Act of 1990 as amended (CCDBG Act); section 418 of the Social Security Act; Consolidated Appropriations Act, 2001 (Pub. L. 106–554).

FOR FURTHER INFORMATION CONTACT: Shannon Rudisill, Director of Technical Assistance, Child Care Bureau, at 202–205–8051.

Dated: September 27, 2005.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 05–19650 Filed 9–30–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005P–0376]

Iceberg Water Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Canada's Original ICEBERG Water Corp., to market a product designated as ''Canada's Original Iceberg Water'' that deviates from the U.S. standard of identity for bottled water. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

DATES: This permit is effective for 15 months, beginning on the date the permit holder introduces or causes the introduction of the test product into interstate commerce, but not later than January 3, 2006.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Canada's Original ICEBERG Water Corp., 23 Lesmill Rd., suite 304, Toronto, Ontario Canada, M3B–3P6.

The permit covers limited interstate marketing tests of products identified as ''Canada's Original Iceberg Water'' that deviate from the U.S. standard of identity for bottled water (§165.110 (21 CFR 165.110)) in that the source of the water is an iceberg. The test product meets all the requirements of the standard with the exception of the source definition. The purpose of this permit is to test the product throughout the United States, in order to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

This permit provides for the temporary marketing of 500,000 cases of the 24 x 500 milliliter bottles and 500,000 cases of the 12 x 1 liter bottles, totaling 1 million cases per year. The total fluid quantity covered by this application is 12 million liters (3,170,065 gallons). The test product will be manufactured for Canada's Original ICEBERG Water Corp., by Discovery Springs, Daniel's Point Rd., Trepassey, Newfoundland, Canada A0A–4B0. Canada's Original ICEBERG Water Corp. will distribute the test products throughout the United States. The information panel of the labels will bear nutrition labeling in accordance with 21 CFR 101.9. The bottled water will be manufactured in accordance with the quality standards in §165.110 and the requirements for processing and bottling of bottled drinking water in 21 CFR part 129. This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than January 3, 2006.

Dated: September 22, 2005.

Barbara Schneeman,

Director, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition.

[FR Doc. 05–19728 Filed 9–30–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0394]

Food and Drug Administration's Communication of Drug Safety Information; 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 Center's current risk communication strategies for human drugs. The public hearing announced in this notice is part of the agency's ongoing effort to improve CDER's risk communication. The purpose of the public hearing is to obtain public input on CDER's current risk communication tools, identify stakeholders for collaboration and implementation of additional tools, and obtain greater understanding of the strengths and weaknesses of CDER's existing risk communication.

DATES: The public hearing will be held on December 7 and 8, 2005, from 8 a.m. to 4:30 p.m. Submit written or electronic notices of participation and comments for consideration at the hearing by November 7, 2005. Written or electronic comments will be accepted after the hearing until January 9, 2006. The administrative record of the hearing will remain open until January 9, 2006.

ADDRESSES: The public hearing will be held at the National Transportation and Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594 (Metro: L'Enfant Plaza Station on the Green, Yellow, Blue, and Orange Lines). Submit written or electronic notices of participation and comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852; *http://www.fda.gov/dockets/ecomments*. Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm* approximately 30 days after the hearing.

FOR FURTHER INFORMATION CONTACT: Lee Lemley, Office of Executive Programs (HFD–006), Center for Drug Evaluation and Research, Food and Drug Administration, 5515 Security Lane, rm. 5107, Rockville, MD 20852, 301–443–5575.

SUPPLEMENTARY INFORMATION:

I. Background

FDA approves human drugs and therapeutic biologics when the agency determines that the benefits of using a product outweigh the risks for the intended population and use. Once a drug product is marketed, however, ensuring its safety becomes a complicated responsibility shared by many parties. These include health care professionals (who must weigh both the risks and the benefits of drugs in deciding whether to prescribe a particular drug for a particular patient to achieve an optimal therapeutic outcome); patients and caregivers (who must understand both the benefits and risks of drugs so they can have informed discussions with their health care professionals about their medicines and make informed decisions about their use); manufacturers, and others. Therefore, it is critical that risk communication be timely, accurate, and easily accessible. Information must also be communicated in a way that recognizes health literacy limitations, including the needs of a multicultural population.

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. In February 2005, the Department of Health and Human Services Secretary Mike Leavitt and former FDA Commissioner Lester Crawford announced plans to establish new communication channels and expand existing channels to provide targeted drug safety information to the public.

Although outside the scope of this hearing, FDA-approved human drug labeling is the primary tool the agency uses to communicate risk and benefit to the public. However, CDER also provides drug safety information to the public through a variety of other risk communication tools. For example, FDA has recently initiated communication tools called Patient and Healthcare Professional Information Sheets. In addition, FDA releases Talk Papers, Public Health Advisories, Press Releases, MedWatch Safety Updates and a monthly video news program for health professionals called the Patient Safety News. FDA also conducts educational campaigns and conveys drug safety information through the CDER Internet site (*http://www.fda.gov/cder*).

II. Scope of the Hearing

FDA is interested in obtaining public comment on the following risk communication tools:

- Patient Information Sheets (for example, see: *http://www.fda.gov/cder/drug/infosheets/patient/adderallpt.htm*)
- Healthcare Professional Information Sheets (for example, see: *http://www.fda.gov/cder/drug/infosheets/hcp/fluoxetinehcp.htm*)
- Talk Papers (for example see: *http://www.fda.gov/opacom/hpnews.html*)
- Public Health Advisories (for example, see: *http://www.fda.gov/cder/news/pubpress.htm*)
- Press Releases (for example, see: *http://www.fda.gov/opacom/hpnews.html*)
- MedWatch Listserv Safety Updates (*http://www.fda.gov/medwatch/index.html*)
- Patient Safety News (*http://www.fda.gov/psn*)
- CDER Educational Campaigns (for example see: *http://www.fda.gov/cder/drug/analgesics/default.htm*)
- CDER Internet site (*http://www.fda.gov/cder*)

Specifically, FDA is inviting public comment from external stakeholders on the following issues:

1. What are the strengths and weaknesses of the communication tools listed previously in this section of the document?
2. What information is available about awareness, use, and perceptions of the effectiveness of these communication tools by health care professionals and by the public in general?
3. Do these tools provide the right kind and amount of risk and other information that health care professionals need to make informed decisions about whether to prescribe drug products, and that the public needs to make informed decisions about whether to use those products?
4. How easily accessible and understandable are FDA's Internet-based sources of drug information?
5. To what extent do CDER's patient-focused communication tools provide useful information for people with low health literacy skills?
6. What mechanisms should CDER consider to convey risk information to special populations (e.g., elderly, non-English speaking)?

The following topics are outside the scope of this hearing: Consumer medication information (and the draft guidance entitled ''Useful Written Consumer Medication Information [CMI]''); industry promotional materials, including Direct to Consumer Advertising; drug labeling (including Medication Guides and patient package inserts); and the draft guidance entitled ''FDA's 'Drug Watch' for Emerging Drug Safety Information.'' Comments have been solicited on these issues at other times in separate proceedings.

III. Notice of Hearing Under 21 CFR Part 15

The Acting Commissioner of Food and Drugs (the Acting 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 Acting 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 Division of Dockets Management (see **ADDRESSES** and **DATES**). To ensure timely handling, any outer envelope should be clearly marked with the docket number listed in brackets in the heading of this notice along with the statement ''FDA's Communication of Drug Safety Information; Public Hearing.'' Groups should submit two written copies. The notice of participation should contain the potential presenter'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 the 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 of the time allotted to the presenter and the approximate time that presenter's oral testimony 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 schedule will be placed on file in the Division of Dockets Management (see **ADDRESSES**) under the docket number listed in brackets in the heading 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 (21 CFR part 10, subpart C). Under § 10.205 (21 CFR 10.205), representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). The transcript will be available on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm*, and orders for copies of the transcript can be placed at the meeting or through the Division of Dockets Management (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 these provisions as specified in § 15.30(h).

IV. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic notices of participation and comments for consideration at the hearing (see **DATES**). Submit a single copy of written or electronic notices of participation and comments, or two paper copies of any mailed notices of participation and comments, except that individuals may submit one 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.

Dated: September 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–19759 Filed 9–30–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0330]

Draft Guidance for Industry and FDA Review Staff on Collection of Platelets by Automated Methods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods'' dated September 2005. The draft guidance provides blood establishments and FDA staff revised recommendations for the collection of Platelets by automated methods (plateletpheresis). The draft guidance is intended to help blood establishments ensure donor safety and the safety, purity, and potency of Platelets collected by an automated blood cell separator device. For the purpose of this document, Platelets collected by automated methods will be referred to by the product name ''Platelets, Pheresis.'' The draft guidance contains recommendations for appropriate criteria for a biologics license application or supplement for manufacturing Platelets, Pheresis. When finalized, this draft guidance will replace the October 1988 ''Revised Guideline for the Collection of Platelets, Pheresis.''

DATES: Submit written or electronic comments on the draft guidance by January 3, 2006, to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance 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*.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods'' dated September 2005. The draft guidance provides blood establishments and FDA staff revised recommendations for the collection of Platelets by automated methods (plateletpheresis). FDA has received new information since the issuance of the October 1998 ''Revised Guideline for