FDA's Web site at *http://www.fda.gov/transparency* along with the agenda for this meeting. The complete case studies will be available in the same locations after the public meeting.

III. Issues for Discussion

The discussion of the three issues described in the following section of this document should not be limited by current statutes or regulations, as the proposals the Task Force develops may include recommendations for changes to current law.

A. Emerging Safety Issues Concerning FDA-Regulated Products

When FDA receives safety information associated with a marketed FDA-regulated product, e.g., medical device, drug, biologic, dietary supplement, cosmetic, or food (including ingredients and food additives), FDA evaluates the information in deciding whether and what actions to take, such as regulatory action regarding the product. FDA will continue to receive, gather, and evaluate additional information to further inform its decisions.

During this process, while still evaluating the situation, FDA may communicate with the public based on the agency's current analysis of the available information about the situation. For example, the agency may issue an early communication about its ongoing safety review of a drug, device, or biologic, or may issue an early communication advising consumers not to eat a certain type of food that may be linked to a foodborne illness or to stop using a certain dietary supplement that may be associated with adverse events.

The Task Force is interested in discussing the principles the agency should use when deciding whether to issue an early communication about a potential problem with an FDA-regulated product. For example, when is it appropriate, or not appropriate for the agency to advise the public about a possible, but unconfirmed foodborne illness outbreak or to issue an early communication about an emerging safety issue with a medical product, dietary supplement, or cosmetic? If appropriate, how should this information be conveyed to the public so that it is useful and does not cause unfounded or unnecessary concern about the product? And what mechanisms (e.g., Internet, mass media, cell phones, direct outreach to health professional and patient organizations) should FDA use to effectively reach the target audiences in a timely manner?

B. Product Applications That Are Abandoned (Which Means That No Work is Being Done or Will Be Undertaken to Have the Application Approved) or Withdrawn By the Applicant Before Approval

The Task Force is interested in discussing the principles and considerations the agency should apply to disclosure of data contained in product applications that are abandoned during the approval process or withdrawn before approval by the applicant. The Task Force would also like to receive comments on whether the considerations governing treatment of these data should depend on the reason the product application was abandoned or withdrawn.

C. Communicating Agency Decisions About Pending Product Applications

The Task Force is interested in discussing what information about pending product applications should be disclosed. Should the agency inform the public when:

- A marketing application seeking approval of a drug or biologic is submitted to the agency for review?
- A marketing application seeking approval or clearance of a medical device is submitted to the agency for review?

When the agency does not approve a marketing application for a drug or biologic, it issues a letter that informs the applicant of FDA's determination not to approve the application in its current form, identifying all apparent deficiencies in the application. Should the agency disclose to the public a determination not to approve a marketing application for a drug or biologic? What, if any, information should the agency disclose about the determination not to approve the application? What, if any, information contained in the response letter should the agency disclose? What principles should the agency apply in making these determinations?

When the agency does not approve a premarket application (PMA) for a medical device, it may issue a ''not approvable'' letter that informs the applicant of FDA's determination not to approve the application in its current form. When the agency does not clear a device submitted through the 510(k) process, a ''not substantially equivalent'' (NSE) letter is issued to the applicant. Should the agency disclose to the public a determination not to approve or clear a marketing application for a medical device? What, if any, information should the agency disclose about the determination not to approve or clear the application? What, if any, information contained in the not approvable letter or the NSE letter should the agency disclose? What principles should the agency apply in making these determinations?

IV. Request for Comments

Regardless of attendance at the public meeting, interested persons may submit written or electronic comments (see **ADDRESSES**). Submit a single copy of electronic comments to *http://www.regulations.gov* 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. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: September 29, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23916 Filed 10–2–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Customs and Border Protection

Agency Information Collection Activities: Delivery Ticket

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension of an existing collection of information: 1651–0081.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Delivery

Ticket. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)).

DATES: Written comments should be received on or before December 4, 2009, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Office of Regulations and Rulings, 799 9th Street, NW., 7th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., 7th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs burden to respondents or record keepers from the collection of information (a total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Delivery Ticket.

OMB Number: 1651–0081.

Form Number: Form 6043.

Abstract: This collection of information requires warehouse proprietors, carriers, Foreign Trade Zone operators and others to prepare a CBP Form 6043 (Delivery Ticket) to cover the receipt of the merchandise and its transport from the custody of the arriving carrier. The information is to be used by CBP officers to document transfers of imported merchandise between parties.

Current Actions: There are no changes to the information collection. This submission is being made to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 1000.

Estimated Number of Annual Responses per Respondent: 200.

Estimated Number of Total Annual Responses: 200,000.

Estimated Time per Response: 20 minutes.

Estimated Total Annual Burden Hours: 66,000.

Dated: September 29, 2009.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E9–23820 Filed 10–2–09; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–1858–DR; Docket ID FEMA–2008–0018]

Georgia; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Georgia (FEMA–1858–DR), dated September 24, 2009, and related determinations.

DATES: *Effective Date:* September 24, 2009.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 24, 2009, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Georgia resulting from severe storms and flooding beginning on September 18, 2009, and continuing, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Georgia.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance in the designated areas, Hazard Mitigation throughout the State, and any other forms of assistance under the Stafford Act that you deem appropriate. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs. If Public Assistance is later requested and warranted, Federal funds provided under that program will also be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Gracia B. Szczech, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Georgia have been designated as adversely affected by this major disaster:

Cherokee, Cobb, Douglas, and Paulding Counties for Individual Assistance.

All counties within the State of Georgia are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. E9–23957 Filed 10–2–09; 8:45 am]

BILLING CODE 9111–23–P