

information on electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance that provides recommendations related to reports under section 905(j) of the FD&C Act (21 U.S.C. 387e(j)), as amended by the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111-31). Section 905(j) authorizes FDA to establish the form for the submission of information related to substantial equivalence. The guidance is intended to assist persons submitting reports under section 905(j) of the FD&C Act. It explains, among other things, FDA's interpretation of the statutory sections related to substantial equivalence, and provides recommendations on the form and content of section 905(j) reports. The guidance also provides information on FDA's review of 905(j) reports.

**II. Significance of Guidance**

FDA is issuing this guidance document as a level 1 guidance consistent with FDA's GGP's (§ 10.115 (21 CFR 10.115)). The guidance discusses premarket statutory requirements that include certain submissions to be made to FDA no later than March 22, 2011. This guidance document is being implemented immediately without prior public comment under § 10.115(g)(2) because the Agency has determined that prior public participation is not feasible or appropriate, as interested parties need clarity as to FDA's expectations regarding 905(j) reports and sufficient time to prepare submissions in advance of the statutory deadline.

Manufacturers of tobacco products first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, must submit the report no later than March 22, 2011, or the tobacco product can no longer be legally marketed. If a 905(j) report is submitted prior to March 23, 2011, the tobacco product may continue to be marketed unless FDA issues an order that the tobacco product is not substantially equivalent to the predicate tobacco product (section 910(a)(2)(B) of the FD&C Act (21 U.S.C. 387j(a)(2)(B)), as

amended by the Tobacco Control Act). It is important that this guidance be available in advance of March 23, 2011, to assist manufacturers in preparing 905(j) reports.

For 905(j) reports for tobacco products first marketed between February 15, 2007, and March 22, 2011 (many of which are from small manufacturers) that are submitted prior to March 23, 2011, FDA intends to allow manufacturers who have acted diligently in preparing their submissions a reasonable amount of time to supplement their initial submissions, provided these manufacturers submit a 905(j) report by the statutory deadline. FDA intends to determine what constitutes a reasonable period of time on a case-by-case basis.

This guidance 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.

**III. Paperwork Reduction Act of 1995**

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information in this guidance was approved under OMB control number 0910-0673.

**IV. Comments**

This guidance document is being implemented immediately without prior public comment under § 10.115(g)(2) because the Agency has determined that prior public participation is not feasible or appropriate, as interested parties need clarity as to FDA's expectations regarding 905(j) reports and sufficient time to prepare submissions in advance of the statutory deadline. You may submit written comments to FDA on this guidance at any time for Agency consideration; in addition, we request that you submit any comments regarding any significant oversight in this guidance within 30 days of the issuance of this guidance (refer to the title page of the guidance for the issue date). Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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. FDA will review any comments we receive and revise the guidance document when appropriate.

**V. Electronic Access**

An electronic version of the guidance document is available on the Internet at <http://www.regulations.gov> and <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: January 3, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-1950-DR; Docket ID FEMA-2010-0002]

**Arizona; 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 Arizona (FEMA-1950-DR), dated December 21, 2010, and related determinations.

**DATES:** *Effective Date:* December 21, 2010.

**FOR FURTHER INFORMATION CONTACT:** Peggy Miller, Office of Response and Recovery, 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 December 21, 2010, 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 Arizona resulting from severe storms and flooding during the period of October 3-6, 2010, 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 Arizona.

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 Public Assistance and Hazard Mitigation in the designated area. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

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

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

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

The Sovereign Tribal Nation of the Havasupai Tribe for Public Assistance.

The Sovereign Tribal Nation of the Havasupai Tribe is 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. 2010-33360 Filed 1-5-11; 8:45 am]

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**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

**[Internal Agency Docket No. FEMA-1951-DR; Docket ID FEMA-2010-0002]**

**Vermont; 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 Vermont (FEMA-1951-DR), dated December 22, 2010, and related determinations.

**DATES:** *Effective Date:* December 22, 2010.

**FOR FURTHER INFORMATION CONTACT:**

Peggy Miller, Office of Response and Recovery, 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 December 22, 2010, 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 Vermont resulting from a severe storm during the period of December 1-5, 2010, 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 Vermont. 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 Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

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

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

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

Chittenden, Franklin, and Lamoille Counties for Public Assistance.

All counties within the State of Vermont 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.*

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**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

**[Internal Agency Docket No. FEMA-1951-DR; Docket ID FEMA-2010-0002]**

**Vermont; Amendment No. 1 to Notice of a Major Disaster Declaration**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Vermont (FEMA-1951-DR), dated December 22, 2010, and related determinations.

**DATES:** *Effective Date:* December 23, 2010.

**FOR FURTHER INFORMATION CONTACT:**

Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Craig A. Gilbert, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Albert Lewis as Federal Coordinating Officer for this disaster.

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