

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This draft guidance is not subject to Executive Order 12866.

## II. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <https://www.regulations.gov>.

Dated: May 29, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4364-DR; Docket ID FEMA-2018-0001]

#### North Carolina; 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 North Carolina (FEMA-4364-DR), dated May 8, 2018, and related determinations.

**DATE:** The amendment was issued on May 17, 2018.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

**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, Glen Sachtleben, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Elizabeth Turner 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 and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**Brock Long,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2018-11874 Filed 6-1-18; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Docket ID FEMA-2018-0002; Internal Agency Docket No. FEMA-B-1831]

#### Changes in Flood Hazard Determinations

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

**ACTION:** Notice.

**SUMMARY:** This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents

of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

**DATES:** These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

**ADDRESSES:** The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

**FOR FURTHER INFORMATION CONTACT:** Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472 (202) 646-7659, or (email) [patrick.sacbibit@fema.dhs.gov](mailto:patrick.sacbibit@fema.dhs.gov); or visit the FEMA Map Information eXchange (FMIX) online at [https://www.floodmaps.fema.gov/fhm/fmx\\_main.html](https://www.floodmaps.fema.gov/fhm/fmx_main.html).

**SUPPLEMENTARY INFORMATION:** The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any

existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the

respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

**David I. Maurstad,**

*Deputy Associate Administrator for Insurance and Mitigation (Acting), Department of Homeland Security, Federal Emergency Management Agency.*

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Arizona:						
Maricopa .....	City of El Mirage (18-09-0120P).	The Honorable Lana Mook, Mayor, City of El Mirage, 10000 North El Mirage Road, El Mirage, AZ 85335.	City Hall, 14405 North Palm Street, El Mirage, AZ 85335.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Aug. 10, 2018 ....	040041
Maricopa .....	City of Surprise (18-09-0120P).	The Honorable Sharon Wolcott, Mayor, City of Surprise, 16000 North Civic Center Plaza, Surprise, AZ 85003.	Public Works Department, Engineering Development Services, 16000 North Civic Center Plaza, Surprise, AZ 85374.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Aug. 10, 2018 ....	040053
Mohave .....	Town of Colorado City (17-09-2669P).	The Honorable Joseph Allred, Mayor, Town of Colorado City, P.O. Box 70, Colorado City, AZ 86021.	Town Hall, 25 South Central, Colorado City, AZ 86401.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Aug. 13, 2018 ....	040059
Mohave .....	Unincorporated Areas of Mohave County (17-09-2669P).	The Honorable Gary Watson, Chairman, Board of Supervisors, Mohave County, 700 West Beale Street, Kingman, AZ 86402.	Mohave County Administration Building, 700 West Beale Street, Kingman, AZ 86402.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Aug. 13, 2018 ....	040058
California: Riverside.	City of Desert Hot Springs (18-09-0176P).	The Honorable Scott Matas, Mayor, City of Desert Hot Springs, 65950 Pierson Boulevard, Desert Hot Springs, CA 92240.	Planning Department, 65950 Pierson Boulevard, Desert Hot Springs, CA 92240.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Aug. 10, 2018 ....	060251
Florida: St. Johns ..	Unincorporated Areas of St. Johns County (18-04-2271P).	The Honorable Henry Dean, Chairman, St. Johns County Board of Commissioners, St. Johns County Administration, 500 San Sebastian View, St. Augustine, FL 32084.	St. Johns County, Permitting Center, 4040 Lewis Speedway, St. Augustine, FL 32084.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Aug. 17, 2018 ....	125147
Minnesota:						
Dakota .....	City of Coates (18-05-2617P).	The Honorable Craig Franzmeier, Mayor, City of Coates, 3033 160th Street East, Rosemount, MN 55068.	City Clerk's Office, 15970 Comstock Avenue, Rosemount, MN 55068.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Aug. 10, 2018 ....	270728
Dakota .....	Unincorporated Areas of Dakota County (18-05-2617P).	The Honorable Kathleen A. Gaylord, Chair, Dakota County Board of Commissioners, Dakota County Administration Center, 1590 Highway 55, Hastings, MN 55033.	Dakota County Administration Center, 1590 Highway 55, Hastings, MN 55033.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Aug. 10, 2018 ....	270101
Nevada: Douglas ..	Unincorporated Areas of Douglas County (17-09-1559P).	The Honorable Steve Thaler, Chairman, Board of Commissioners, Douglas County, P.O. Box 218, Minden, NV 89423.	Douglas County Community Development, 1594 Esmeralda Avenue, Minden, NV 89423.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Aug. 23, 2018 ....	320008
New York:						
Dutchess .....	Town of Washington (18-02-0573P).	The Honorable Gary E. Ciferri, Supervisor, Town of Washington, P.O. Box 667, Millbrook, NY 12545.	Washington Town Hall, 10 Reservoir Drive, Millbrook, NY 12545.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Sep. 28, 2018 ....	361147

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Dutchess .....	Village of Millbrook (18-02-0573P).	The Honorable Rod Brown, Mayor, Village of Millbrook, P.O. Box 349, Millbrook, NY 12545.	Village of Millbrook, 35 Merritt Avenue, Millbrook, NY 12545.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Sep. 28, 2018 ....	360219
Ohio: Warren .....	City of Springboro (18-05-0285P).	The Honorable John Agenbroad, Mayor, City of Springboro, 320 West Central Avenue, Springboro, OH 45066.	Springboro Municipal Building, 320 West Central Avenue, Springboro, OH 45066.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Aug. 10, 2018 ....	390564
Texas: Dallas .....	Town of Highland Park (18-06-0588P).	The Honorable Joel T. Williams, III, Mayor, Town of Highland Park, 4700 Drexel Drive, Highland Park, TX 75205.	Public Works Department, 4700 Drexel Drive, Highland Park, TX 75205.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Aug. 3, 2018 .....	480178
Washington: Kittitas .....	City of Ellensburg, (17-10-1541P).	The Honorable Bruce Tabb, Mayor, City of Ellensburg, City Hall, 501 North Anderson Street, Ellensburg, WA 98926.	City Hall, 501 North Anderson Street, Ellensburg, WA 98926..	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Aug. 17, 2018 ....	530234
Kittitas .....	Unincorporated Areas of Kittitas County, (17-10-1541P).	The Honorable Laura Osiadacz, Chairman, Board of Commissioners, Kittitas County, 205 West 5th Avenue Suite 108, Ellensburg, WA 98926.	Kittitas County Community Development Services, 411 North Ruby Street Suite 1, Ellensburg, WA 98926.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Aug. 17, 2018 ....	530095

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**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-4365-DR; Docket ID FEMA-2018-0001]

**Hawaii; 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 Hawaii (FEMA-4365-DR), dated May 8, 2018, and related determinations.

**DATES:** The declaration was issued May 8, 2018.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, in a letter dated May 8, 2018, 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 Hawaii resulting from severe storms, flooding, landslides, and mudslides during the period of April 13-16, 2018, 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 Hawaii.

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 be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

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, Dolph A. Diemont, of FEMA is appointed to act as the

Federal Coordinating Officer for this major disaster.

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

The City and County of Honolulu and Kaua'i County for Public Assistance.

All areas within the State of Hawaii are eligible 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.

**Brock Long,**

*Administrator, Federal Emergency Management Agency.*

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