

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials."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 This draft guidance is not subject to Executive Order 12866.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Persons with access to the internet may obtain the draft guidance at 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.*

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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.