

## Waiver Notice

Pursuant to section 319(a) of the Public Health Service (PHS) Act, 42 U.S.C. § 247d, Secretary Becerra has determined that public health emergencies (PHEs) exist as a result of the consequences of Hurricane Helene, with PHEs declared on September 23, 2024, for the state of Florida; September 24, 2024, for the state of Georgia; September 25, 2024, for the states of North Carolina and South Carolina; and September 26, 2024, for the state of Tennessee. Additionally, the PHE for Hurricane Milton was renewed on October 5, 2024, for the state of Florida.

The Secretary's determination to declare the PHEs was made after consultation with public health officials as necessary. As a result of the PHEs, the Secretary also determined pursuant to section 319(f) of the PHS Act that circumstances of the PHEs necessitate a waiver from the requirements of the Paperwork Reduction Act (PRA), 44 U.S.C. § 3501 *et seq.*, effective as of the date of this notice. The waiver is justified to collect information to support the Department of Health and Human Services' response to supply chain constraints for Food and Drug Administration (FDA)-regulated products resulting from the hurricanes. This waiver applies to information to be collected by FDA the related to its "immediately in effect" guidance documents.

Pursuant to the waiver, the requirements of 44 U.S.C. § 3501 *et seq.* shall not be applicable with respect to voluntary collection of information during the effective time period.

The PRA waiver is effective as of October 11, 2024 and is anticipated to remain in effect throughout the time period of the immediate investigation and response to the emergencies declared pursuant to section 319(a) of the PHS Act, and for a reasonable length of time for immediate post response review regarding the PHE.

Any initiative subject to this waiver that is ongoing after the termination of the effective period shall be subject to the requirements of the Paperwork Reduction Act within 30 days of expiration of the waiver. The waiver applies to the voluntary information collection related to the Hurricanes Helene and Milton PHE undertaken by the FDA.

This notice will be updated as needed.