SMG 1410.422

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Medical Devices and Radiological Health

Device Shortages

Effective Date: 18 August 2021

1. Authority Delegated and To Whom Delegated.

A. The officials listed below are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356j), as added by the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 27 March 2020, with respect to medical devices including:

- receiving and responding to notifications of a discontinuance or interruption in manufacturing of certain devices;
- prioritizing and expediting inspections or review of applications;
- distributing information on such discontinuances or interruptions in manufacturing;
- issuing notices of noncompliance with section 506J; and
- maintaining and publishing a device shortages list.

(1) Center for Devices and Radiological Health (CDRH) Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

(2) CDRH/Office of Product Evaluation and Quality (OPEQ) Director and Deputy Directors.

(3) CDRH/Office of Strategic Partnerships and Technological Innovation (OSPTI) Director and Deputy Director.

(4) CDRH/OSPTI/Division of All Hazards Response, Science, and Strategic Partnerships (DAHRSSP) Director and Deputy Director.

(5) CDRH/OSPTI/DAHRSSP/All Hazard Readiness Response and Cybersecurity (AHRRC) Assistant Director.

2. Redelegation.

These officials may not redelegate these authorities.

3. Effective Date.

The Acting Commissioner of Food and Drugs approved this delegation, via memorandum, on 18 August 2021.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	08/18/2021	N/A	CDRH/ OP	Janet Woodcock, M.D. Acting Commissioner of Food and Drugs