

SMG 1410.33

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – General Redelegation of Authority

Certification Following Inspections

Effective Date: 18 December 2020

1. Authority Delegated and To Whom Delegated.

- A. The officials listed below are authorized to issue “Certificates of Sanitary Construction” and “Certificates of Sanitation” under 21 CFR Section 1240.20:
- (1) Office of Regulatory Affairs (ORA) Office of Human and Animal Food Operations (OHAFO) Assistant Commissioner for Human and Animal Food Operations.
 - (2) ORA/OHAFO/Office of Human and Animal Food East (OHAFOE) Program Director for Human and Animal Food Operations East.
 - (3) ORA/OHAFO/OHAFOE/Division of Human and Animal Food Operations East I (DHAFOE I) Director.
 - (4) ORA/OHAFO/OHAFOE/DHAFOE I/Human and Animal Food Investigations Branch Chief.
 - (5) ORA/OHAFO/OHAFOE/Division of Human and Animal Food Operations East II (DHAFOE II) Director.
 - (6) ORA/OHAFO/OHAFOE/DHAFOE II/Human and Animal Food Investigations Branch Chief.
 - (7) ORA/OHAFO/OHAFOE/Division of Human and Animal Food Operations East III (DHAFOE III) Director.
 - (8) ORA/OHAFO/OHAFOE/DHAFOE III/Human and Animal Food Investigations Branch Chief.
 - (9) ORA/OHAFO/OHAFOE/Division of Human and Animal Food Operations East IV (DHAFOE IV) Director.
 - (10) ORA/OHAFO/OHAFOE/DHAFOE IV/Human and Animal Food Investigations Branch Chief.
 - (11) ORA/OHAFO/OHAFOE/Division of Human and Animal Food Operations East V (DHAFOE V) Director.
 - (12) ORA/OHAFO/OHAFOE/DHAFOE V/Human and Animal Food Investigations Branch Chief.

- (13) ORA/OHAFO/OHAFOE/Division of Human and Animal Food Operations East VI (DHAFOE VI) Director.
- (14) ORA/OHAFO/OHAFOE/DHAFOE VI/Human and Animal Food Investigations Branch Chief.
- (15) ORA/OHAFO/Office of Human and Animal Food West (OHAFOW) Program Director for Human and Animal Food Operations West.
- (16) ORA/OHAFO/OHAFOW/Division of Domestic Human and Animal Food Operations (DDHAFO) Director.
- (17) ORA/OHAFO/OHAFOW/Division of Human and Animal Food Operations West I (DHAFOW I) Director.
- (18) ORA/OHAFO/OHAFOW/DHAFOW I/Human and Animal Food Investigations Branch Chief.
- (19) ORA/OHAFO/OHAFOW/Division of Human and Animal Food Operations West II (DHAFOW II) Director.
- (20) ORA/OHAFO/OHAFOW/DHAFOW II/Human and Animal Food Investigations Branch Chief.
- (21) ORA/OHAFO/OHAFOW/Division of Human and Animal Food Operations West III (DHAFOW III) Director.
- (22) ORA/OHAFO/OHAFOW/DHAFOW III/Human and Animal Food Investigations Branch Chief.
- (23) ORA/OHAFO/OHAFOW/Division of Human and Animal Food Operations West IV (DHAFOW IV) Director.
- (24) ORA/OHAFO/OHAFOW/DHAFOW IV/Human and Animal Food Investigations Branch Chief.
- (25) ORA/OHAFO/OHAFOW/Division of Human and Animal Food Operations West V (DHAFOW V) Director.
- (26) ORA/OHAFO/OHAFOW/DHAFOW V/Human and Animal Food Investigations Branch Chief.
- (27) ORA/OHAFO/OHAFOW/Division of Human and Animal Food Operations West VI (DHAFOW VI) Director.
- (28) ORA/OHAFO/OHAFOW/DHAFOW VI/Human and Animal Food Investigations Branch Chief.

2. Redelegation.

These officials may not further redelegate this authority.

3. Effective Date.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 18 December 2020.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	04/02/2001	N/A	OC/ OA/ OM/OMP	Bernard Schwetz Acting Commissioner of Food and Drugs
Revision	04/04/2011	N/A	ORA/ ORM	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	05/06/2013	N/A	OGROP/ ORA/ ORM	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	12/29/2017	N/A	OGROP/ ORA/ OM	Scott Gottlieb, M.D. Commissioner of Food and Drugs
Revision	12/18/2020	N/A	ORA/ OPOP	Stephen M. Hahn, M.D. Commissioner of Food and Drugs