

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - BIOLOGICS

**DELEGATIONS OF AUTHORITY FOR VARIOUS ISSUANCES RELATED TO
HUMAN CELL, TISSUE, AND CELLULAR AND TISSUE-BASED PRODUCTS
(HCT/Ps)**

Effective Date: 07/07/2005

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED.

- A. The following officials are authorized to perform the functions of the Commissioner, under section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, in issuing warning letters, untitled letters, and other written notices or warnings to manufacturers of human cell, tissue, or cellular or tissue-based products (HCT/Ps):
1. Director and Deputy Center Directors, Center for Biologics Evaluation and Research (CBER); the Director and Deputy Director, Office of Compliance and Biologics Quality, (OCBQ), CBER; and
 2. Regional Food and Drug Directors, District Directors, and Chiefs of District Compliance Branches.
- B. The following officials are authorized to perform the functions of the Commissioner, under section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, in issuing orders for retention, recall, or destruction of HCT/Ps:
1. Director and Deputy Center Directors, CBER; the Director and Deputy Director, OCBQ, CBER; and
 2. Regional Food and Drug Directors and District Directors.
- C. The following officials are authorized to perform the functions of the Commissioner, under section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, in issuing orders for cessation of manufacturing involving HCT/Ps: the Director and Deputy Center Directors, CBER.

2. REDELEGATION.

These officials may not further redelegate these authorities.

3. EFFECTIVE DATE.

The effective date of this delegation of authority is July 7, 2005.