

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug and Biological Product Consolidation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

DMB

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Certified *G. P. Pinsky*

SUMMARY: The Food and Drug Administration (FDA) is transferring certain product oversight responsibilities from the Center for Biologics Evaluation and Research (CBER) to the Center for Drug Evaluation and Research (CDER). This consolidation initiative provides the opportunity to further develop and coordinate scientific and regulatory activities between CBER and CDER. FDA believes that as more drug and biological products are developed for a broader range of illnesses, such interaction is necessary for both efficient and consistent agency action.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. The Consolidation Initiative

A. Therapeutic Biological Products Transferred to CDER

As of June 30, 2003, responsibility for regulating most therapeutic biologics, with certain exceptions (e.g., cell and gene therapy products and therapeutic vaccines) will be transferred from the Office of Therapeutics Research and Review (OTRR), CBER, to the Office of New Drugs (OND), and the Office of Pharmaceutical Science (OPS), CDER. Initially, this transfer of products will take place as the divisions of OTRR within CBER are detailed to offices within CDER. As of June 30, 2003:

- The Division of Therapeutic Proteins and the Division of Monoclonal Antibodies of OTRR, CBER, will be detailed to OPS, CDER.
- The Division of Clinical Trial Design and Analysis, the Division of Application Review and Policy, and the immediate office of the Director, OTRR, CBER, will be detailed to OND, CDER.

FDA anticipates that as of the start of fiscal year 2004 on October 1, 2003, the offices detailed to CDER will be incorporated into CDER's organizational structure, including the creation of a new Office of Drug Evaluation (ODE) in OND, CDER.

B. Therapeutic Biological Products Remaining in CBER

Under a previous reorganization, cell and gene therapy products from the Division of Cellular and Gene Therapies, OTRR, CBER were transferred to a new office, the Office of Cellular, Tissue and Gene Therapies (OCTGT).

Overall responsibility for therapeutic vaccines will remain in CBER. The clinical review of therapeutic vaccine-associated investigational new drug applications (INDs) and biologics license applications (BLAs) will be

conducted by CBER and coordinated with the consolidated clinical expertise area in CDER.

II. Web Site Listing CBER Applications Transferred to CDER and Contact Information

FDA has created a Web site listing the identification numbers of the INDs, BLAs, investigational device exemptions, and new drug applications in CBER that are being transferred to CDER. Holders of all CBER applications are encouraged to check this Web site to determine which, if any, of their applications are being transferred and to find new contact information. The Web site address is: *<http://www.fda.gov/cber/transfer/transfer.htm>*. Until notified by CDER, submitters should continue to send submissions to the CBER Document Control Center.

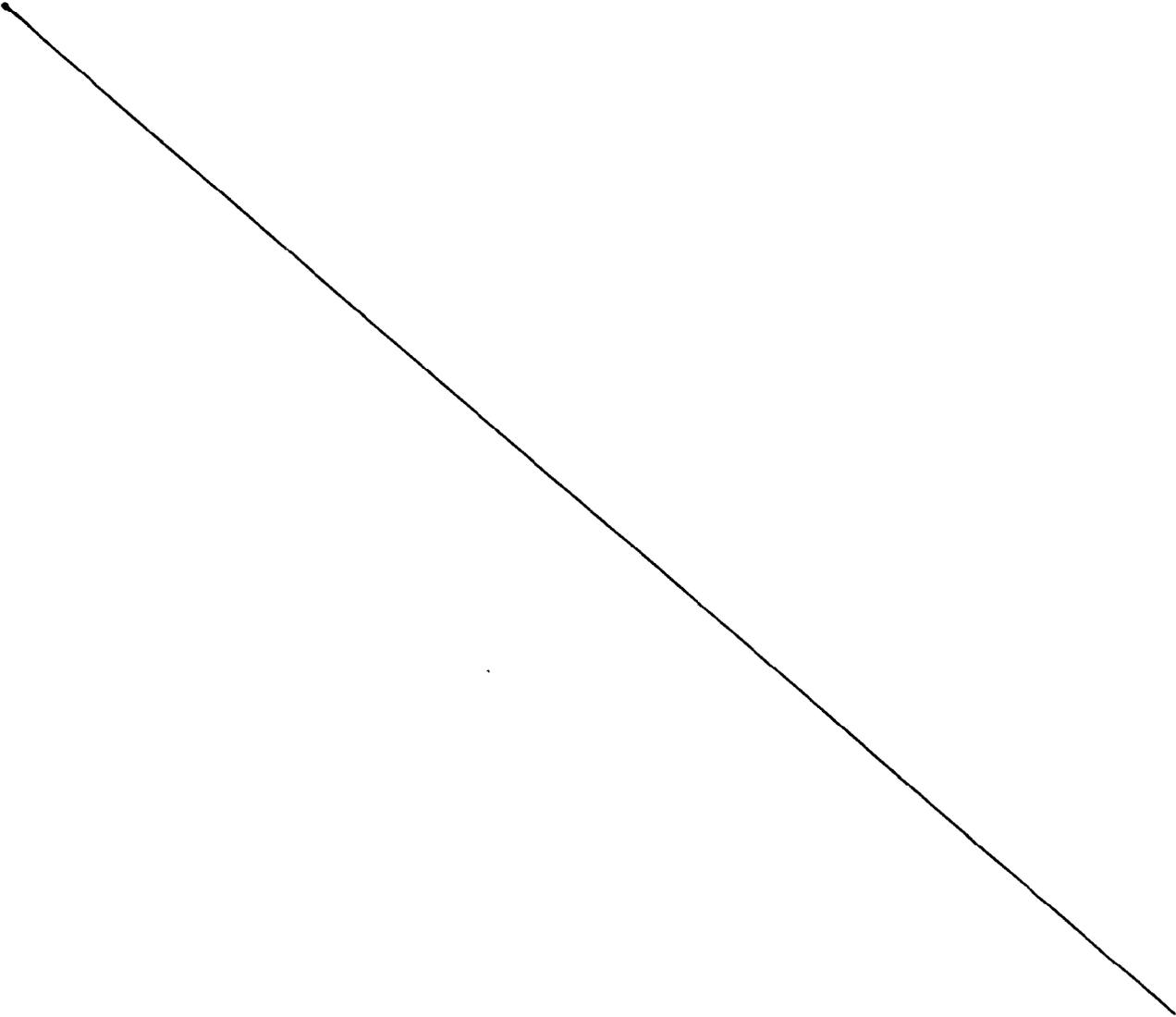
III. Delegations of Authority

As a result of this product consolidation and the resulting changes to the organizational structure of CDER and CBER, the agency has conducted a comprehensive update of the delegations of authority to reflect organizational changes. Current program delegations of authority for CDER and CBER have been revised to reflect these changes. Delegations of authority give particular officials in the Centers the legal authority needed to take substantive actions and perform certain functions of the Commissioner of Food and Drugs. These changes will be made to the agency's Staff Manual Guide (SMG) system available on the Internet at *<http://www.fda.gov/smg>*. While comprehensive changes have been made to the delegations, the agency believes the current delegation at SMG 1410.702 provides CDER with all necessary authority for the premarket approval of any biological product for which CDER has oversight. Furthermore, revised SMG 1410.202 provides CDER with the

necessary authority to perform all functions of the Director of CBER with respect to biological products transferred to CDER.

IV. Regulations Affected by the Product Consolidation

The agency is in the process of making technical amendments to its regulations affected by this reorganization and anticipates these revisions will be completed by the beginning of fiscal year 2004 on October 1, 2003, or



shortly thereafter. Any revisions to FDA's regulations will be published in the **Federal Register** upon completion.

Dated: 6/20/03
June 20, 2003.



Jeffrey Shuren
Assistant Commissioner for Policy.

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