

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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Certifier	W. Reese

Temporary Deferment of Activities Relating to Certain Biologics Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Center for Biologics Evaluation and Research (CBER) will be converting its current biologics license application (BLA) data base system into a new data base system. During the period required for this conversion, the agency will temporarily defer certain submissions subject to CBER review and approval, and the review period, if any, on pending submissions will be suspended. FDA plans to temporarily defer action on submissions related to BLA's, product license applications (PLA's), establishment license applications (ELA's), and any related correspondence. FDA is also requesting that sponsors voluntarily refrain from filing the affected submissions during this period. FDA estimates that the deferment period will be about 1 month.

FOR FURTHER INFORMATION CONTACT: Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-2000.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 *et seq.*) and section 351 of the Public Health Service Act (42 U.S.C. 262), CBER is responsible for receiving, reviewing, evaluating, and taking appropriate action on a variety of submissions concerning various regulated products, including: (1) Investigational new drug applications (IND's) and investigational device exemption applications (IDE's) for certain products for which CBER has been assigned responsibility; (2) BLA's, PLA's, and ELA's submitted for biological products;

and (3) new drug applications (NDA's), premarket approval applications (PMA's), and premarket notifications (510k's) for which CBER has been assigned responsibility.

In an effort to upgrade CBER's data base and tracking system for license applications, CBER is converting to a new data base system starting in June 2000. Because of this conversion, CBER will be unable to start work or continue work on certain pending submissions and reports until conversion to the new system is ready; therefore, FDA plans to temporarily defer action on certain submissions subject to CBER review and approval, including BLA's, PLA's, ELA's, and related correspondence. Other submissions subject to CBER review and approval, including IND's, NDA's, 510k's, PMA's, or IDE's will not be affected by the conversion and temporary deferment. FDA is requesting that applicants voluntarily refrain from filing the affected submissions during the conversion period, which will begin on June 26, 2000, and is expected to continue until July 20, 2000. CBER will try to complete the conversion and begin processing submissions sooner than the specified timeframe. Confirmation of the resumption of normal review procedures and any change in this timeframe will be announced on the Internet on CBER's home page at <http://www.fda.gov/cber/genadmin.htm>.

FDA anticipates that this period will be about 1 month or less. Although FDA will continue to accept mail during this period, affected submissions and related correspondence will neither be officially logged in nor will review of affected submissions or related correspondence begin. Any review period will not begin until the conversion is completed and CBER review functions resume. CBER will attempt to keep the mail in the order of the day received. When work resumes, the mail will be handled in the order in which it was received. Also, the review periods on pending submissions will be suspended during the conversion period. The action due date for all pending submissions will be extended by the length of the actual deferment. CBER will attempt to minimize the period during which regular procedures are suspended.

Persons who may be affected by this temporary deferment should call the contact person listed above or CBER's Office of Communication, Training, and Manufacturer's Assistance at 301-827-2000 with any questions regarding the conversion.

Dated: 6/14/00
June 14, 2000

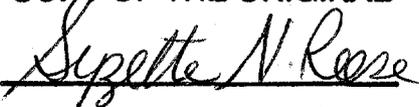


Margaret M. Dotzel,
Associate Commissioner for Policy.

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Suzette N. Reese