This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

Memorandum

DATE: October 30, 1992 RB92-G

FROM: Director, Division of Cardiovascular, Respiratory, and Neurological Devices (DCRND)

SUBJECT: Policy for Expiration Dating

TO: DCRND Staff

It has been brought to my attention that the 510(k) regulations do not explicitly address the issue of expiration dating, and we have been challenged by at least one 510(k) submitter for this requirement. Thus this memo restates our policy and will be added as a Redbook Memorandum.

The following is our policy:

- Any device reviewed under a 510(k) must contain an expiration date if the predicate device contains an expiration date.
- If the predicate device does not contain an expiration date, the new device must be packaged and sealed in the identical manner as the predicate device in order for the new device to be found substantially equivalent without having an expiration date.
- If the predicate device does not contain an expiration date and the new device is to be packaged differently and/or the device is made of different materials that raise concerns about long term stability beyond those posed by the predicate, the new device must contain an expiration date.
- Determination of the expiration date involves assessing the barrier properties of the packaging to assure sterility. In addition, certain devices must be tested to assure that storage and shipping conditions do not alter their function and that they will function the same as when manufactured. For example, batteries in devices such as pacemakers should still be within specification at the expiration date.
- All devices cleared through the PMA process must contain an expiration date.