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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 24 1981

TO: ALL MANUFACTURERS AND IMPORTERS OF MICROWAVE OVENS

SUBJECT: Retention of Records Required by 21 CFR 1002

The Food and Drug Administration has recently issued a compliance policy guide to its field offices concerning the retention of records on results of testing microwave ovens during manufacture. We are enclosing a copy of this policy for your information and use.

We are hopeful that this policy will reduce the burden of compliance with the recordkeeping requirements. Please note that, in addition to this policy to shorten the retention time of production records, the annual report guide was changed to eliminate the summary of production test data.

If you have any questions or comments on the policy, please call the Microwave/Acoustics Section at 301 - 443-6540.

Sincerely yours,

Walter E. Gundaker
Acting Director
Division of Compliance
Bureau of Radiological Health

Enclosure

SUBJECT: Retention of Microwave Oven Test Records

BACKGROUND:

During recent factory inspections several manufacturers of microwave ovens expressed concern over the need to retain the results of tests for electronic product radiation safety. Such records, as required by 21 CFR 1002.30(a)(2) must be retained for a period of five years as specified in 21 CFR 1002.31. As a result of the rapidly increasing production rates, the quantity of such test records has resulted in storage problems. The Bureau has been requested to provide some relief for this situation. The FDA agrees that the public health or safety will not be adversely affected if guidance is established that would shorten the retention period for some records.

The tests for electronic product radiation safety that are conducted by microwave oven manufacturers (for which records must be kept) can be broken down into the following categories:

(1) The tests performed on each oven on the production line prior to boxing the unit. This is often referred to as the "final compliance test."

(2) The tests conducted on sampled units that are subjected to short or long-term life or endurance testing.

(3) The tests conducted on units selected for sampling or audit.

(4) The tests conducted on sampled units to evaluate the side effects of transportation, vibration or shock.

(5) The tests conducted on sampled units to evaluate the effects of the environment, sensitivity to load placement, cavity temperature, etc., or the product safety.

The guidance established in this guide pertains only to the preservation of the results of the final compliance tests (item 1 above).

POLICY:

The results of the following final compliance tests must be recorded:

(1) The results of the RF leakage tests conducted on the fully assembled unit. This is often called the final or compliance RF test.

(2) The results of RF leakage tests with only the secondary interlock operating if the product design necessitates that such a test be conducted on each unit.

(3) The results of the function test of the required safety interlocks and monitor circuit. This can be recorded as an "accept/reject" entry on the record.

The above test results should be recorded by model number, serial number and production date. The records of the tests should be filed, either hard copy or computer storage, as a unit that encompasses the 12 month production period from July 1 through June 30. This corresponds to the production period covered by the annual report that is submitted to the FDA by September 1, of each year.

Presently it is required that the results of the tests conducted on each unit be retained for five years after the date of the test. FDA will not object to each manufacturer retaining the unit of test records for only one year after the end of the production period, as shown in the following example:

> A unit of test records has been filed by a manufacturer to cover the results of testing for the production period of July 1, 1979 through June 30, 1980. The manufacturer has summarized the results in the required annual report to BRH. This unit of records must be retained until June 30, 1981, one year after the end of the production period.

Since this record preservation guidance is effective immediately, the records of the production line radiation safety tests conducted prior to July 1, 1979 may be discarded. Manufacturers should note clearly that this policy pertains only to the records for the production line of final compliance tests and not to the records of the results of the other safety tests mentioned in this guidance document. These records, as well as the records required by 21 CFR 1002.30(b)(1) and the records received from dealers or distributors pursuant to 21 CFR 1002.41 are to be maintained for five years.