CPG Sec. 130.400 Use of Microfiche and/or Microfilm for Method of Records Retention

BACKGROUND:

The agency has received many questions concerning the use of microfiche and/or microfilm systems in lieu of the retention of original records. This Compliance Policy Guide is based on a May 11, 1979 response to a request for an Advisory Opinion on this subject. (Docket Number 77A-0270).

POLICY:

The Food and Drug Administration has ** published several regulations that permit the maintenance of certain recordkeeping systems in lieu of the retention of original records: good manufacturing practices for medical devices (43 FR 31508, July 21, 1978); good manufacturing practices for human and veterinary drugs (43 FR 45014, September 29, 1978); nonclinical laboratory studies (43 FR 59986, December 22, 1978). These regulations include the use of microfiche and/or microfilm. We therefore conclude that the utilization of a microfiche and/or microfilm reduction system in lieu of the retention of original pre-clinical, clinical, and related drug and medical device research records, and drug and medical device quality control and manufacturing records, is acceptable.

The preambles to these regulations, and the regulations, discuss the conditions applicable to the maintenance of reduction systems. These include the following:

1. All records must be readily available for review and copying by FDA investigators at any reasonable time.
2. All necessary equipment must be provided to facilitate viewing and copying of the records.
3. A reproduction must be a true and accurate copy of the original record. Thus, where the reproduction process results in a copy that does not reveal changes or additions to the original record, the original must be retained.

Also, the reproduced copy and any image shown on a viewing screen must note, in a suitable manner, that an alteration has been made and that the original record is available.

Material between asterisks is new or revised

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