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.

FDA POLICY FOR THE REGULATION OF COMPUTER PRODUCTS

11/13/89 - D R A F T

I. Purpose

To the extent that computer products used in medicine are intended to affect the diagnosis and treatment of patients and thus are medical devices, the Food and Drug Administration (FDA) must provide reasonable assurance that these products are safe and effective. To clarify its role in this area, FDA has prepared this general policy statement on how it will determine whether a computer product is a medical device and if so how FDA will regulate it.

Although the document provides general guidance on the regulatory requirements for computer products, it cannot cover all issues in advance. Manufacturers of such products are encouraged to contact FDA with questions they may have. For general information on the regulation of medical devices, contact the Division of Small Manufacturers Assistance at 1-800-638-2041. For questions specific to computer products and their regulation as medical devices, contact the Division of Product Surveillance at 1-301-427-1144. For questions about blood bank products, contact the Center for Biologics Evaluation and Research, Office of Compliance, Inspections and Surveillance Staff at 1-301-295-8191.

II. Authority

FDA is responsible for assuring the safety and effectiveness of medical devices under the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (the Act). Computer products are subject to regulation as medical devices when they meet the following definition (see Section 201(h) of the Act, amended by Section 3(a)(1) of P.L. 94-295):

> "... an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is ... (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals ... (3) intended to affect the structure or any function of the body of man or other animals."

III. Policy

FDA's device regulations and authorities do not apply to computer products intended only for use as traditional "library" functions such as storage, retrieval, and dissemination of medical information -- functions traditionally carried out through textbooks and journals. Similarly, FDA's device regulations and authorities do not apply to computer products intended only for use as general accounting or communications functions or those solely intended for educational purposes rather than to diagnose or treat patients.

When a computer product is a "similar or related article, including any component, part, or accessory ..." of a product recognized as a medical device in its own right, the computer product is regulated according to the requirements of its parent device (unless the computer product is separately classified).

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Computer products which are medical devices, and not components, parts, or accessories of other articles which are themselves medical devices, are subject to one of four levels of regulatory control, depending on their characteristics. These products are regulated with the least degree of control necessary to provide reasonable assurance of safety and effectiveness.

The following describes each level of regulation for computer products.

A. Existing Exemptions from Registration, Listing, and Premarket Notification, and Proposed Exemptions from Good Manufacturing Practice (GMP) Requirements Provided by Implementation of This Policy.

Manufacturers of the following categories of medical computer products are currently exempt from the requirements for registering their establishments and listing their products with FDA, for reporting adverse effects under the Medical Device Reporting (MDR) Regulation, and for Premarket Notification. Manufacturers of the following categories of medical computer products also will be exempt from complying with the GMP regulations by FDA promulgating new exemptions to implement this policy. Manufacturers of such devices are, however, subject to the misbranding and adulteration provisions of the Act. FDA can thus address public health concerns which might be posed by such devices.

1. General Purpose Articles (21 CFR 807.65(c))

A general purpose article is a product that is not labeled or promoted for medical uses but which, by virtue of its application in health care, meets the definition of a medical device. These devices either pose little or no risk, or are appropriately the sole responsibility of the health care professionals who have used them in medical applications. A personal computer which has been programmed by a clinical chemist to display values from tests on human specimens is an example of a general purpose article. A database management system, with no medical claims, that is used by a health care professional to identify patients at risk for a given medical procedure is a general purpose article.

2. Computer Products Manufactured by Licensed Practitioners for Use in Their Practice (21 CFR 807.65(d))

This exemption applies to "Licensed practitioners including physicians, dentists and optometrists who manufacture or otherwise alter devices solely for use in their practice." A medical institution where a computer product is developed will be treated similarly, provided that the product is intended only for use in that institution. This exemption applies only where there is no commercial distribution. For example, exchange of information on public "bulletin boards" would not result in a requirement for manufacturers of the software to register or list their devices.

3. Computer Products Used in Teaching and Non-Clinical Research (21 CFR 807.65(f))

This exemption applies to "Persons who manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis ... " This exemption covers manufacturers with research and development efforts which have not progressed to the stage of human experimentation.

B. Future Exemptions from Registration, Listing, Premarket Notification, MDR, and GMP Requirements for Certain Products.

These exemptions will be limited to manufacturers of previously unclassified information management products (i.e., computer products which are medical devices, because they meet the definition of a medical device as described above in Section II, but not including traditional library or accounting functions as described above in Section III). Manufacturers of computer products (e.g., "expert" or "knowledge based" systems, artificial intelligence and other types of decision support systems) that are intended to involve competent human intervention before any impact on human health occurs, (e.g., where clinical judgment and experience can be used to check and interpret a system's output) will be exempt from Registration, Listing, Premarket Notification, and compliance with the MDR and GMP regulations.

These exemptions will be accomplished by FDA through the normal exemption granting procedures. Manufacturers of new devices that are substantially equivalent to these newly classified preamendments devices will likewise be exempted. In the interim, manufacturers of such unclassified products and similar postamendments devices will not be required to register or list these computer products, notify FDA prior to marketing, report under the MDR regulations, or comply with the GMP regulations. These additional exemptions do not apply to manufacturers of computer hardware and software devices intended for use in blood banks.

C. Computer Products for Which FDA Must Be Notified Prior to Marketing.

The manufacturers of postamendments or classified preamendments devices that have been significantly modified are subject to the premarket notification requirement, and will be required to notify FDA prior to marketing. Manufacturers of preamendments devices that were not classified by FDA in its original classification efforts and which do not meet the criteria in III.B., above, are not subject to the exemptions in III.B., even in the absence of a classification regulation. Manufacturers of computer products not exempt from the Premarket Notification requirements and found by FDA to be substantially equivalent to a device classified into Class I, II, or III, will be regulated to the same degree as the equivalent preamendments or postamendments device. For such products, if not exempt under this policy, the manufacturers must register with FDA, list their products, notify FDA prior to marketing, and meet all other requirements of the device's class.

D. Computer Products for Which Premarket Approval May be Required.

Computer products in this category are subject to the greatest degree of regulatory control. Those devices which are not substantially equivalent to a preamendments device, or which are substantially equivalent to a Class III device, are Class III devices. The safety and effectiveness of new Class III devices must be demonstrated by the manufacturer before marketing, usually through a Premarket Approval Application (PMA). If a manufacturer believes that a PMA is not necessary prior to marketing to assure safety and effectiveness, FDA encourages the submission of a petition to reclassify the product to a lower class. At this time, FDA is not aware of any computer product that is not a component, part, or accessory of another device that would require an approved PMA prior to marketing.