FDA POLICY FOR THE REGULATION OF COMPUTER PRODUCTS

I. Purpose

To the extent that computer products used in medicine are intended to affect the diagnosis and treatment of patients and 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 as medical devices contact the Division of Small Manufacturers Assistance (800) 638-2041. For questions specific to computer products and their regulation as medical devices contact the Division of Product Surveillance at (301) 427-8156.

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 used only for traditional "library" functions such as storage, retrieval, and dissemination of medical information—functions traditionally carried out through textbooks and journals. Similarly, computer products used for general accounting or communications functions are not covered, nor are those used solely for educational purposes rather than to diagnose or treat patients.

When a computer product is a "component, part, or accessory" of a product recognized as a medical device in its own right, the computer component is regulated according to the requirements for the parent device (unless the component of the device is separately classified). This would include any computer product which is intended to have a direct interface with a medical device or one whose primary function is to provide input data intended to control the functioning of a medical device.

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 three degrees 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 manufacturers of these products could be: (A) exempt from registering and listing their products with FDA; (B) required to register and list as well as to notify FDA before marketing; or (C) required to obtain FDA approval by demonstrating safety and effectiveness before marketing a product.

The following describes each level of regulation for computer products.
A. Exemptions From Registration, Listing, and Premarket Notification

Manufacturers of the following categories of medical computer products are exempt from the requirements for registering their establishments and listing their products with FDA, for reporting adverse effects under the Medical Device Reporting Regulation, and for premarket notification. 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 if they should arise.

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 facility where a computer product is developed will be treated similarly, provided that the product is used only in that facility. Furthermore, if software is provided without charge to other similar medical facilities, no requirement to register will be incurred. Thus, for example, exchange of software on computer "bulletin boards" would not result in a requirement for registration or listing.

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 research and development efforts which have not progressed to the stage of human experimentation.

Computer products including, for example, many software products known as "expert" or "knowledge based" systems, that are intended to involve competent 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 also be exempt from registration, listing, and premarket notification. This will be accomplished by FDA through the normal exemption granting procedures. New devices that are substantially equivalent to these newly classified preamendments devices will likewise be exempt. In the interim, manufacturers of such unclassified products and similar postamendments devices will not be required to register, or list these computer products, or notify FDA prior to marketing.

B. Computer Products for Which FDA Must be Notified Prior to Marketing

1. Computer Products with Uses Excluding Competent Human Intervention

Manufacturers of postamendments and preamendments devices that are intended to be used without competent human intervention will not be exempt from the premarket notification requirement, and will be required, under 21 CFR 807.81(a)(3), to notify FDA prior to marketing.

2. Substantially Equivalent Computer Products

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. In these cases, the manufacturer must register with FDA, list his products, notify FDA prior to marketing, and meet all other requirements of the device's class.

C. 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 regulated as 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 (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.
IV. Brief Description of Regulatory Classes

Class I devices are subject to the act's "general controls" relating to such matters as misbranding, registration of manufacturers, recordkeeping, and good manufacturing practices. An example is a program for the calculation of the composition of infant formulas.

Class II devices are those for which general controls are insufficient to provide reasonable assurance of safety and effectiveness, and for which performance standards can provide such assurance. A computer program designed to produce radiation therapy treatment plans is such a device.

Class III devices are those for which insufficient information exists to assure that general controls and performance standards will provide reasonable assurance of safety and effectiveness. Generally, these devices are represented to be life-sustaining or life-supporting, or for a use which is of substantial importance in preventing impairment to health, are implanted in the body, or present a potential unreasonable risk of illness or injury. Postamendments devices (new devices introduced into the marketplace after the Amendments were enacted May 28, 1976) which are found not substantially equivalent to a preamendments device are Class III devices, as is a postamendments device that is found to be "substantially equivalent" to a Class III preamendments device. At present, all Class III computer devices are components, parts, or accessories of other products recognized as medical devices in their own right and are regulated as such as discussed in Part III, supra. An example is a device having a computerized component which measures glucose levels and based upon measured results, calculates and dispenses insulin without physician intervention.
FDA DRAFT POLICY GUIDANCE FOR THE REGULATION OF COMPUTER PRODUCTS; AVAILABILITY

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Draft FDA Policy for the Regulation of Computer Products" prepared by FDA's Center for Devices and Radiological Health (CDRH). The document being made available clarifies how FDA would apply existing statutory requirements to hardware and software computer products marketed for medical use.

DATE: Comments by (insert date 60 days after date of publication in the FEDERAL REGISTER).

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Requests for single copies of the draft policy should be sent to Charles Furfine (address below).

86-525
FOR FURTHER INFORMATION CONTACT:

Charles Furfine,
Center for Devices and Radiological Health (HFZ-84),
Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857,
301-443-4874.

SUPPLEMENTARY INFORMATION: FDA is making available for
public comment draft policy guidance for the regulation of
computer products. The draft policy guidance clarifies how
FDA would apply existing statutory requirements to the
regulation of computer products (i.e., both hardware and
software) when such products meet the definition of a
medical device in the Medical Device Amendments of 1976 (the
amendments) to the Federal Food, Drug, and Cosmetic Act (the
act) (21 U.S.C. 301-392). A device is defined in section
201(h) of the act as "* * * 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." (21 U.S.C. 321(h).)
Under the draft policy, FDA would not regard computer products used only for traditional "library" functions such as storage, retrieval, and dissemination of information—functions traditionally carried out through textbooks and journals—to be medical devices subject to regulation by the agency. Similarly, the policy notes that FDA's device regulations and authorities also would not apply to computer products used for general accounting or communications functions or solely for instructional purposes, rather than to diagnose or treat patients.

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

Computer products which are medical devices, and not components, parts, or accessories of other articles which are themselves medical devices, are regulated with the least degree of control necessary to provide reasonable assurance of safety and effectiveness. For example, many software products known as "expert" or "knowledge based" systems
that are not used with existing medical devices and 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) are exempt from registration, listing, premarket
notification, and premarket approval requirements. FDA is
also not aware of any computer product that is not a
component, part, or accessory of another device that would
require an approved premarket approval application (PMA)
before marketing.

The agency is cognizant of the need to safeguard First
Amendment protections and recognizes that, in some cases, it
may be difficult to make a clear distinction between
software products that perform traditional "book" or
"library" functions, and software products that fall within
the definition of a medical device under the draft policy,
based on their intended use in the diagnosis or management
of health-related conditions. FDA believes flexible
guidance is necessary for effective implementation of the
medical devices law and specifically invites comments on the
appropriateness of the approach taken in the draft policy.

Interested persons may, on or before (insert date 60
days after date of publication in the FEDERAL REGISTER),
submit written comments to the Dockets Management Branch
(address above). Two copies of any comments should be
submitted, except that individuals may submit one copy.
Comments are to be identified with the docket number found in brackets in the heading of this document. The draft policy document and comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1987

Frank E. Young
Commissioner of Food and Drugs

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Carolyn L. Conrad