



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

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JAN 21 2000

David F. Weeda, et al.
Olsson, Frank, and Weeda, P.C.
1400 Sixteenth Street, NW, Suite 400
Washington, D.C. 20036-2220

Re: Docket No. 97P-0039/CP1

Dear Mr. Weeda:

This responds to your citizen petition, dated January 28, 1997 and submitted pursuant to 21 C.F.R. § 10.30, on behalf of the Association of Independent Blood Centers, Inc. ("AIBC"), a not-for-profit association representing 32 community blood centers in 12 states. In your petition, you request that the United States Food and Drug Administration ("FDA" or "the agency") "recognize, and so inform industry, that computer software developed by blood centers for their own use is not subject to the device premarket notification requirements." In your petition, you make three principal arguments in support of the requested action: (1) that in-house developed blood establishment software is not in "commercial distribution" within the plain meaning of the statute and in light of the legislative history; (2) that such software is a custom device, exempt from 510(k) requirements; and (3) that the regulatory approach of FDA's Center for Biologics Evaluation and Research ("CBER") to blood establishment software is inconsistent with the approach of FDA's Center for Device and Radiological Health ("CDRH") to other software products. The reasons for the alleged inconsistency have not been articulated, and therefore the agency is acting in an arbitrary and capricious manner. In responding to your petition, the agency has reviewed the grounds for your request, the applicable law, and materials in the administrative record. After careful evaluation, the agency denies your petition.

I. Background

FDA described the functions of blood establishment software in a March 31, 1994 letter to manufacturers of blood establishment software (the "March 31, 1994 letter"), that was subsequently printed in the Federal Register at 59 Fed. Reg. 044991, 44992 (Aug. 31, 1994):

97P-0039

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These software products are designed to receive and store data used by blood establishments during the manufacturing process, from determining donor suitability through component processing, testing, and labeling to product release. They are designed to receive and store data regarding blood donor status, including donors' answers to health history questions and the results of laboratory tests, including blood grouping and typing, hepatitis, and antibody to the human immunodeficiency virus (anti-HIV). Blood establishment personnel later access and use the data to determine whether donors are suitable and whether blood or blood components are free from disease-causing agents transmissible by blood, such as hepatitis and HIV. In addition, the data are used to label blood and blood components prior to release for use in hospitals and other health care facilities or for further manufacturing.

It is critical that blood establishment software performs these functions reliably. Nevertheless, blood establishment software has not always performed reliably. FDA investigators have observed numerous problems with blood establishment software, including a number of poorly designed programs that posed significant risks to the public health, such as the potential for release into the blood supply of blood found to be reactive to the human immunodeficiency virus ("HIV"). In many of these instances, unsuitable units of blood actually had been released for transfusion or further manufacture. These observations led to warning letters and recalls of blood and blood products as well as warning letters and recalls involving the defective software itself.

Indeed, the Blood Products Advisory Committee recently considered the risks presented by blood establishment software. One panel member commented, "...The types of defects or problems identified by the FDA are extraordinarily serious. From our standpoint, they are intolerable in terms of the risk to the patients. In point of fact, they seem to far out-shadow the types of concerns in terms of what could be missed..." by blood tests incapable of detecting viral markers during the window of time between initial infection of a blood donor and proliferation of the virus to a level detectable under current tests. Blood Products Advisory Committee Meeting Minutes ("BPAC Minutes"), Mar. 20, 1998, at 79.

In accordance with its plan to assure the safety and effectiveness of blood establishment software, and thereby protect the blood supply, FDA advised manufacturers in its March 31, 1994 letter that blood establishment software met the

definition of a device under the Federal Food, Drug, and Cosmetic Act ("FDC Act" or "Act"), see 21 U.S.C. § 321(h)(2), and informed them that FDA would require a premarket notification for such software pursuant to section 510(k) of the FDC Act, 21 U.S.C. § 360(k) ("510(k) notification").. The letter described why blood establishment software meets the definition of a medical device under the FDC Act, delineated the device requirements as applied to blood establishment software, and requested that within one year, by March 31, 1995, manufacturers make their premarket submissions.¹

After publishing the March 31, 1994 letter, FDA explained in communications with the blood industry that blood establishments that created software for their own use were considered to be manufacturers of blood establishment software, and were therefore required to submit 510(k) notifications with regard to their software. See, e.g., May 7, 1996 letter to AIBC member, attached to Citizen Petition; BPAC Minutes, June 20, 1996, at 30-34; BPAC Minutes, Mar. 20, 1998, at 78.

In your citizen petition, you have challenged FDA's determination with regard to "own use" blood establishment software.

II. Blood Establishment Software Is A Device Under the FDC Act.

The statutory text must be the beginning point for an inquiry into whether the definition of medical "device" encompasses blood establishment software. Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842 (1984). Moreover, "unless they explicitly forbid it, the purpose of a statutory provision is the best text of the meaning of the words chosen." Cawley v. United States, 272 F.2d 443, 445 (2d cir. 1959) (cited with approval in United States v. An Article of Drug *** Bacto-Unidisk, 394 U.S. 784, 799 n.18 (1969)). Accordingly, "remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health." Bacto-Unidisk, 394 U.S. at 798.

¹FDA subsequently extended this date. See October 3, 1995 Federal Register Notice (60 Fed. Reg. 51802), (publishing a February 10, 1995 letter giving manufacturers the one year extension). The agency also advised blood establishments that they could request more time beyond March 31, 1996, to convert to systems with cleared 510(k) notifications.

The FDC Act defines a medical device, in relevant part, as follows:

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 . . .

21 U.S.C. § 321(h). The definition of a medical device is obviously quite broad in scope and encompasses a range of products wider than "any strict medical definition might otherwise allow." Bacto-Unidisk, 394 U.S. at 798. Further, the question of whether a product is a device is one that the agency has jurisdiction to decide, CIBA Corp. v. Weinberger, 412 U.S. 640, 643-44 (1973), and the "'view of the agency administering the statute is entitled to considerable deference.'" Young v. Community Nutrition Inst., 476 U.S. 974, 981 (1986). See also Chevron, 467 U.S. at 844.

Consistent with the Act's purpose to protect the public health, 21 U.S.C. § 321(h) directs FDA to consider the intended use of the product. The intended use of a product determines whether or not it is a device under the FDC Act. United States v. An Article of Device . . . Toftness Radiation Detector, 731 F.2d 1253, 1256-57 (7th Cir.), cert. denied, 469 U.S. 882 (1984). Intended use may be demonstrated in a number of ways, including a product's actual use. United States v. 22 Rectangular or Cylindrical Finished Devices . . . the Sterolizer MD-200, 714 F. Supp. 1159, 1165 (D.Utah 1989) (citing H.R. Rep. No. 853, 94th Cong., 14 (1976)).

Applying this standard, FDA has determined that blood establishment software is a device under 21 U.S.C. § 321(h) because it is an instrument, apparatus, implement, machine, contrivance, or other similar or related article, that is intended for use in the prevention of disease (e.g., hepatitis or Acquired Immune Deficiency Syndrome) in humans in that it is used to facilitate notification of infected donors and to prevent infectious or otherwise harmful blood products from being distributed for transfusion or further manufacturing use. See, e.g., March 31, 1994 letter, 59 Fed. Reg. 44991; 62 Fed. Reg. 1767 (Jan. 13, 1997) ("...software products used in the manufacture or maintenance of data for blood and blood components are devices under (21 U.S.C. § 321(h)) because these products aid in the prevention of disease by identifying unsuitable donors and by preventing the release of unsuitable blood and blood

components for transfusion or for further manufacturing use."); BPAC Minutes, June 20, 1996, at 65-66 (blood establishments rely heavily on the data maintained on software systems; that reliance related to the prevention of disease because it directly impacts the release of blood products.)

Moreover, FDA has determined that the protections afforded the public health through premarket clearance are significant and necessary. A regulatory system that relies solely on post-design validation of products is inadequate to protect the public from the risk that could arise from the release of defective blood and blood products due to a software "glitch." BPAC Minutes, June 20, 1996, at 19 ("continuing problems associated with the use of blood establishment computerized systems led FDA to the conclusion that system validation by the blood establishment was insufficient to correct problems caused by faulty software design and to prevent distribution of unsuitable blood and blood components.") BPAC Minutes, Mar. 20, 1998 at 14 ("regulation of blood establishment software should begin at the design phase.") For this reason, FDA has rejected your suggestion that "blood bank computer software is more appropriately regulated through drug and blood product current good manufacturing practice requirements than through regulation as a device." Citizen Petition at 4.

The agency's determination that blood establishment software is a device is consistent with its approach to the regulation of other products used in blood establishments and elsewhere. For instance, items such as blood grouping reagents and other blood and blood product manufacturing equipment used in the processing of blood products are classified under 21 C.F.R. Part 864, subpart J, of the device regulations. Moreover, FDA regulates as devices other medical equipment intended to prevent disease, such as operating room air filtering systems. See 21 C.F.R. 878.5350; see also, Sterolizer , 714 F. Supp at 1164-65 & n.12 (upholding the agency's determination that a surgical instrument sterilizer is a device).

Finally, although you concede, for purposes of your petition only, that blood establishment software is a device within the meaning of the Act, you nevertheless argue that blood establishment software "...is no more a device than, for example, the computer software used to generate processing or other quality records (e.g., automated complaint handling systems) or to operate automated tableting, encapsulating, and packaging machinery in a drug manufacturing establishment..." which the agency has not considered to be devices. Citizen Petition at 4. The agency rejects this contention. Unlike drug manufacturing

software related exclusively to manufacturing functions such as tableting, blood establishment software is intended to perform multiple functions and thereby prevent disease.² It directly affects health of donors and the safety of the blood supply. The agency appropriately distinguishes between blood establishment software and software related to tableting machines.

Your suggestion that blood establishment software is a relatively insignificant device because "computer systems and software only replace manual recordkeeping that was in use not many years ago," Citizen Petition at 3, similarly ignores the important tasks performed by the device. As an FDA official explained at a 1996 Blood Products Advisory Committee Meeting:

in the late 1980s . . . we were seeing that there was a blossoming, if you will, of increased reliance on computerized system[s] because of an increase in donor screening questions, and due to the suitability decisions, increase in testing. So there was an increased need to manage that data.

BPAC Minutes, June 20, 1996, at 42. Thus, conditions changed in the industry. It became necessary to automate data functions that previously could be performed, carefully, by humans. FDA has recognized that conditions have forced increased reliance on blood establishment software, and has taken steps to assure that the device will perform reliably.

III. Blood Establishment Software is in Commercial Distribution Within the Meaning of the Act.

²As you yourself note, blood establishment software products are designed:

to receive and store data regarding blood donor status, including donors' answers to health history and lifestyle questions and the results of laboratory tests on donor blood samples. These computer data are used at a later time by blood establishment personnel to determine whether individuals are suitable donors, and whether blood and blood components are free from detectable disease-causing agents transmissible by blood, such as hepatitis and HIV. The computer software is typically also designed to store and process data regarding component processing, testing, labeling, product release, and distribution for use in healthcare facilities or for further manufacturing.

Citizen Petition at 2.

The Act requires persons who propose "to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use," to provide a 510(k) notification to the agency "at least ninety days before making such introduction or delivery." 21 U.S.C. § 360(k). You contend that blood establishment software that is intended to prevent disease in humans and is either distributed across state lines or used to transfer data across state lines, is not in commercial distribution, and, therefore, that this provision does not apply. The agency has considered your arguments and concluded that they are without merit.

A. Blood Establishment Software is "Held for Sale."

Courts have held that an article is held for sale if it is used for any purpose other than personal consumption. See United States v. Articles of Device (Acuflex, Pro-Med), 426 F. Supp. 366, 368 n.3 (W.D.Pa.1977). "All articles . . . not intended for consumption by the producer, are designed for sale." Hipolite Egg Co. v. United States, 220 U.S. 45, 54 (1911).

Applying this principle, courts have recognized that medical practitioners who hold devices and use them to treat patients are holding those devices for sale within the meaning of the FDC Act. United States v. Diapulse Corp. of America, 514 F.2d 1097, 1098 (2d Cir.), cert. denied, 423 U.S. 838 (1975) ("such devices, used in the treatment of patients, may properly be considered 'held for sale'"); Accuflex, 426 F. Supp. at 368 n.3 (device used by medical practitioners for diagnosis and treatment of patients was "held for sale"); United States v. Article of Device ... Cameron Spitler Amblyo-Syntonizer, 261 F. Supp. 243, 246 (D. Neb. 1966) (device was held for sale because "[a]lthough the claimant never sold the devices in the commercial sense, the device was used in the claimant's treatment of patients.")

In this instance, blood establishments are using software in the business of manufacturing blood and blood products. Such software is created for use in the business; it is not intended for personal consumption. In a very real sense, blood establishment software is actually used in the treatment of patients, both recipients of blood and blood products and donors. Cf. Bacto-Unidisk ("drug" within the meaning of FDC Act includes article intended to be used in the laboratory as a screening test to help choose the antibiotic to use in treating a particular infection in a patient). It assists in the treatment of recipients by protecting them from the transmission of diseases,

including HIV and hepatitis, and by protecting them from receiving improperly labeled products. Proper labeling affords recipients significant protections. It assures that recipients will receive products bearing accurate expiration dates and lot codes, which will facilitate the recall of distributed product. It protects recipients from the infusion of blood products labeled with the wrong blood type (e.g., the infusion of AB Positive blood into an individual with O Negative blood type) - a mistake that can cause serious injury and even death. Moreover, blood establishment software assists in the treatment of blood donors by facilitating notification to them of the results of tests performed on the donor's blood. This notification, in turn, facilitates speedy commencement of treatment, and allows the donor to take steps to protect others against infection. Your suggestion that blood establishment software "is not used to treat patients," Citizen Petition at 9 n.1, ignores the software's critical role in treatment. Accordingly, FDA rejects it.

Nor does the fact that blood establishments do not impose a separate charge for the blood establishment software "treatment," mean that they are not holding the device for sale. See Citizen Petition at 3. In United States v. 1800.2625 Wine Gallons, the court held that the statutory provision regarding products that are adulterated or misbranded while they are "held for sale" after shipment in interstate commerce, 21 U.S.C. § 331(k), applied "whether the article is thereafter sold or given away." 121 F. Supp. 735, 738-39 (W.D.Mo. 1954). Even a bailee, who had no title to the adulterated goods but was holding them for another person, was holding for sale within the meaning of the Act. United States v. Wiesenfeld Warehouse Co., 376 U.S. 86, 92 (1964).

In sum, blood establishment software, is a medical device. By using that software in blood establishment operations and on blood establishment patients (recipients and donors), blood establishments hold it for sale.

B. The Software is in "Commercial Distribution"
Because it is "Held for Sale"

You correctly note that the Act does not provide a definition of "commercial distribution." Citizen Petition at 5. Through notice and comment rulemaking, the agency has defined "commercial distribution" in this context as "any distribution of a device intended for human use which is held or offered for sale." 21 C.F.R. § 807.3(b); see also 42 Fed. Reg. 42520 (Aug. 23, 1977). The agency's use of the concept of "held for sale" in defining commercial distribution is meant to differentiate products distributed or to be distributed in commerce from those not intended for commercial purposes, in harmony with congressional intent. As a longstanding interpretation of the FDC Act, which FDA is charged with administering, FDA's interpretation is entitled to considerable deference. Community Nutrition Inst., 476 U.S. at 981. In applying this rule here, FDA has reasonably required such blood establishment software manufacturers to comply with the § 510(k) notification provisions of 21 U.S.C. § 360(k).

Nevertheless, you argue that the agency's interpretation of the statutory term "commercial distribution" should not be accorded deference. First, you contend that the concept of commercial distribution should be understood to be restricted to instances where a seller supplies the article to a buyer, such as a retailer. Citizen Petition at 5-6. However, in constructing this narrow definition, you do not follow the "principle of statutory construction" that you yourself deem to be "well-recognized," Citizen Petition at 6: "A fundamental canon of statutory construction is that, unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning." Perrin v. United States, 444 U.S. 37, 42 (1979). In applying this principle, the agency determined that within the context of the FDC Act, the "ordinary, contemporary, common meaning" of the phrase "commercial distribution" included the concept of "holding articles for sale."

You further note that the concept of "held for sale" has been part of the FDC Act since its enactment in 1938, see 21 U.S.C. § 331(k), but that Congress did not use it in the device amendments of 1976. Accordingly, you contend, Congress did not intend that the phrase "commercial distribution" should encompass the concept of "held for sale." See Citizen Petition at 9.

Your argument appears to refer to a rule of statutory construction that is often summed up in the Latin phrase, "expressio unius est exclusio alterius," meaning that the

specification of one provision implies the exclusion of other provisions not mentioned. That argument is unavailing here. Since the "held for sale" provisions were not enacted contemporaneously with the provisions at issue here, the maxim simply does not apply. "This rule of statutory interpretation . . . has force only if the two provisions in question are included within the same legislative enactment." Halverson v. Slater, 129 F.3d 180, 186 (D.C. Cir. 1997). And even if the maxim were potentially applicable, it would have little persuasive force. The maxim:

"has little force in the administrative setting" where we defer to an agency's interpretation of a statute unless congress has "'directly spoken to the precise question at issue.'" Texas Rural Legal Aid, Inc. v. Legal Serv. Corp., 940 F.2d 685, 694 (D.C. Cir. 1991) (quoting Chevron USA v. NRDC, 467 U.S. 837, 842 (1984)). Expression unius "is simply too thin a reed to support the conclusion that Congress has clearly resolved [an] issue. Id.

Mobile Communications Corp. of America v. F.C.C., 77 F.3d 1399, 1404-05 (D.C. Cir.), cert. denied, 519 U.S. 823 (1996). Indeed, the maxim "is often misused." Shook v. D.C. Fin. Respons. & Mgmt. Assist. Auth., 132 F.3d 775, 782 (D.C. Cir. 1998). See also Cheney R. Co. v. I.C.C., 902 F.2d 66, 68 (D.C. Cir.), cert. denied, 498 U.S. 985 (1990) (discussing limited utility of the maxim, which "[s]cholars have long savaged.")

FDA's interpretation is consistent with the legislative history. In arguing that blood establishment software manufactured for an establishment's own use is not in "commercial distribution" as that term would be generally understood, you note that the 1976 House Committee report discussing the classification provisions of the device amendments states that "'Commercial distribution' is the functional equivalent of the popular phrase 'on the market'. It is not intended to include mere announcements of intent to market a device." Citizen Petition at 7. However, by this language, the Committee simply distinguished between devices commercially distributed before the date of the amendments, and devices that had been announced as forthcoming at some point, but were not in actual commercial distribution. This important distinction assured that products that had not been commercially distributed would not be "grandfathered" as preamendment devices. The Committee did not discuss the well-settled principle that the concept of "commercial distribution" encompassed product that was "held for sale" (see discussion supra at 8-9), and certainly did not

purport to exclude product that was held for sale from the definition of product in commercial distribution.

C. The Interplant Transfer Exemption from the 510(k) Notification Requirement is not Applicable Here.

You note that FDA exempts from the definition of commercial distribution, "[i]nternal or interplant transfer of a device between establishments within the same parent, subsidiary, and/or affiliate company." 21 C.F.R. § 807.3(b)(1). "Establishment" is defined as "a place of business under one management at one physical location at which a device is manufactured, assembled, or otherwise processed." § 807.3(c). You argue that this exemption from the 510(k) notification requirements should be applicable here, and that FDA's failure to apply this regulation is unlawful. Citizen Petition at 9-10.

However, in making this argument, you fail to consider that the reason for the interplant transfer is critical to the applicability of the exemption. The exemption applies only if the transfer is between "establishments." Both of those establishments must be locations where the device "is manufactured, assembled, or otherwise processed." 21 C.F.R. § 807.3(c). Distinct from the situation here, where transfers of software and data are made to users of the software, the interplant transfer exemption is intended to enable manufacturers to ship devices to other device manufacturing, assembling, or processing locations within the same company, e.g., for packaging or labeling, without triggering the 510(k) requirement. See 42 Fed. Reg. 42526 (Aug. 23, 1977) (Preamble to 21 C.F.R. § 807.3) (proposed rule changed to facilitate intraorganizational shipment between a foreign subsidiary and a domestic parent without requirement that company make 510(k) notification before shipment.) Indeed, in the Preamble to this regulation, FDA repeatedly stated that the exemption did not apply to devices held or offered for sale. Id. Thus, FDA has properly concluded that the interplant transfer exemption is inapplicable here.

D. FDA's Compliance Policy Guide Section 300.600 is Irrelevant to FDA's Determination

Section 300.600 of FDA's Compliance Policy Guide ("CPG") is entitled "Commercial Distribution with Regard to Pre-market Notification (Section 510(k))." Despite the relatively broad title, the CPG section concerns a relatively narrow issue: what are the circumstances under which FDA would consider "a device to presently be in commercial distribution and also to have been in commercial distribution before May 28, 1976 (the effective date

of the Medical Device Amendments), even though no units of the device had been delivered to purchasers or consignees before that date" (emphasis supplied).

This provision is inapplicable here for one very obvious reason: you have not asked FDA to make a determination whether blood establishment software was in commercial distribution before May 28, 1976. Thus, FDA rejects your suggestion that FDA has "fail[ed] to follow" this policy. See Citizen Petition at 11. Moreover, in a section of the CPG that you do not quote, FDA explicitly incorporated the concept of "held for sale."³

E. FDA Has Determined That Blood Establishment Software is Not Subject to the 21 C.F.R. § 807.85(a) Exemption from 510(k) Notification Requirements.

F. Section 807.85(a), 21 C.F.R., sets forth, in relevant part, the following exemption from 510(k) notification requirements:

(a) A device is exempt from the premarket notification requirements of this subpart if (1) the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for

³ The CPG states that FDA will consider a device to presently be in commercial distribution and also to have been in commercial distribution before May 28, 1976, even though no units of the device had been delivered to purchasers or consignees before that date:

1. The device was displayed, advertised, or otherwise offered for sale before May 28, 1976, for a specific intended purpose or purposes, with no limitations (e.g., no limitation to research or investigational use);
2. The manufacturer had, before May 28, 1976, accepted, or been prepared to accept, at least one order to purchase the device that resulted, or would have resulted, in a contract of sale for the device in the United States, generally with delivery to occur immediately or at a promised future date;
3. The device was not being offered or accepted only for research or investigational use; and
4. The manufacturer of the device can provide adequate documentation establishing (1) through (3) above to the satisfaction of the Food and Drug Administration.

commercial distribution, and the device meets one of the following conditions:

(1) It is intended for use by a patient named in the order of the physician or dentist (or other specially qualified person); or

(2) It is intended solely for use by a physician or dentist (or other specially qualified person) and is not generally available to, or generally used by, other physicians or dentists (or other specially qualified persons).

You contend that blood establishment software falls within clause (2) of this exemption.

As a threshold matter, analysis of the applicability of this exemption may not even reach clause (2). A blood establishment might indeed "offer" for commercial distribution the software through labeling disseminated to the blood establishment.

Moreover, FDA has determined that in-house blood establishment software does not fall within clause (2) of this exemption. Rather than being "intended solely for use by a physician or dentist (or other specially qualified person)," the device is widely used throughout large blood establishments. Use is not limited to a single physician, dentist, or other specially qualified person. Moreover, it appears likely that very few of the users of the device would qualify as "specially qualified person[s]."⁴ Thus, in light of the number of patients treated with the device, the number of users of the device, and the lack of "special qualifications" of those users, in-house blood establishment software does not fall within this exemption. Cf. 41 Fed. Reg. 37458, 37460 (Sept. 3, 1976) (Preamble to proposed rule) (807.85 provides exemption for devices needed to conform to the special needs of physicians or patients).

⁴You have suggested that FDA should stretch this "specially qualified practitioner" exemption to include an entire blood establishment, functioning on its own as a "specially qualified practitioner." Citizen Petition at 12-13. FDA rejects this suggestion. A blood establishment is run by many different practitioners, of varying levels of qualification. It falls outside the exemption. 21 C.F.R. § 807.85(a).

IV. FDA's Regulation of Blood Establishment Software is Appropriately Designed to Assure the Safety and Effectiveness of the Device.

Finally, you suggest that FDA has unfairly chosen to regulate blood establishment software differently than it regulates other software devices. In making this argument, you rely on a draft policy. Although you do not give the date of that draft policy, you appear to rely on a draft policy dated November 13, 1989 ("1989 Draft Policy"). You admit that the ten year old draft policy expressly excluded blood establishment software from any exemptions under consideration. Citizen Petition at 14.

By excluding blood establishment software from the ambit of the exemptions proposed in the 1989 Draft Policy, the agency signaled early on that the agency recognized that blood establishment software presented unique issues of safety and effectiveness. From the beginning, FDA has indicated that it would regulate blood establishment software in accordance with its review of those issues. Indeed, the FDC Act requires FDA to do so.⁵ In 1993, before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, FDA reiterated its intent to regulate blood establishment software in accordance with the peculiar safety and effectiveness concerns presented by the device. See Statement by David A. Kessler, M.D., before the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce (July 28, 1993). In 1994, in the March 31, 1994 letter, FDA announced its intention to regulate blood establishment software by requiring compliance

⁵When Congress enacted the 1976 Medical Device Amendments to the FD&C Act, 21 U.S.C. §§ 360c-360k, it established a system for classification and premarket clearance of medical devices. The 1976 amendments established three device classes: Class I, Class II, and Class III. Class III devices are the most strictly regulated, see 21 U.S.C. § 360c(a)(1), and must receive premarket approval before release for commercial distribution. 21 U.S.C. § 360e(a); Contact Lens Mfrs. Ass'n v. FDA, 766 F.2d 592, 594 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062(1986). Class II devices are subject to intermediate regulatory requirements, and Class I devices are subjected to minimal regulation. The 1976 amendments assigned FDA the duty to classify devices into one of these three categories, depending on the degree of regulation necessary to assure the safety and effectiveness of the devices for their intended uses. 21 U.S.C. § 360c; United States v. 25 Cases . . . Sensor Pads, 942 F.2d 1179, 1180 (7th Cir. 1991); Contact Lens, 766 F.2d at 594.

with section 510(k) notification requirements. Indeed, FDA explained itself again at the June 20, 1996 meeting of the Blood Products Advisory Committee, and again at the March 20, 1998 meeting. In view of the consistent statements that FDA has made on this subject, even in the 1989 Draft Policy, FDA does not accept your contention that "[t]here has been no articulation of the reasons for this disparity." Citizen Petition at 14.⁶ FDA has not acted arbitrarily or capriciously.

Moreover, the agency rejects your arguments that FDA should abandon the careful work it has done in the area of regulation of blood establishment software, in favor of a regulatory strategy that has yet to be determined by CDRH. Your suggestion that there may exist "a great disparity in the treatment of medical software between" CDRH and CBER, Citizen Petition at 17, is based on a false assumption that all medical devices that are software products should be treated similarly. That assumption runs counter to the FDC Act, which requires FDA to identify the degree of regulation necessary to provide reasonable assurance of the safety and effectiveness of a particular device. See, e.g., 21 U.S.C. § 360c(a)(1). In fact, the 1989 Draft Policy itself announced that the level of regulation of software devices would vary depending on the characteristics of the device. Draft Software Policy at 2.

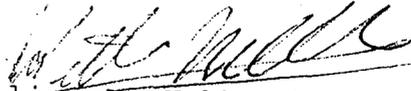
Indeed, FDA has considered the provisions of the Draft Software Policy that you discuss, and has concluded that those provisions should not affect FDA's decisions regarding regulation of blood establishment software.

⁶Since we have taken action with regard to blood establishment software only after careful consideration of the actions required to assure the safety and effectiveness of this device, we reject your suggestion that FDA has failed to avoid unwarranted regulatory restrictions on computer software devices. See Citizen Petition at 15.

V. Conclusion

Your request that FDA recognize, and so inform industry, that computer software developed by blood centers for their own use is not subject to premarket notification requirements, is denied.

Sincerely yours,



William K. Hubbard
Senior Associate Commissioner
for Policy, Planning, and Legislation