



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

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Edward John Allera, P.C., et al.  
Akin, Gump, Strauss, Hauer & Feld, L.L.P.  
1333 New Hampshire Avenue, N.W., Suite 400  
Washington, D.C. 20036

Re: Docket No. 96P-0087/PSA1

Dear Mr. Allera:

This responds to the citizen petition you filed on March 7, 1996, on behalf of a small company that develops software for blood banks. In your petition, you request that the United States Food and Drug Administration ("FDA" or "the agency") stay indefinitely the deadline for premarket submissions for software programs utilized in blood establishments, pending resolution of the issues identified in your petition. In responding to your petition, the agency has carefully evaluated the grounds for your request. Based on consideration of those grounds, the issues they raise, the applicable law, and other materials in the administrative record, your petition is denied.<sup>1/</sup>

I. Background

Since the early 1980s, as computer software grew to play a more important role in treating patients and preventing disease, the agency and groups outside the agency have discussed the regulation of computer software used in medical applications. The discussion has concerned the requirements for computer software under the applicable laws and regulations. In the mid 1980s, FDA formulated a strategy for regulating software,

including software that is used in blood establishments, that was intended to protect the public health without stifling innovation. In 1987, the agency made available for comment a

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<sup>1/</sup>Your petition requests an administrative stay of action. Under 21 C.F.R. § 10.35(b), requests for a stay must be submitted "no later than 30 days after the date of the decision involved." As your petition was filed untimely, see 21 C.F.R. § 10.35 (b), (g), the agency is evaluating your request under the citizen petition provisions, 21 C.F.R. § 10.30, instead. Nonetheless, the agency took into account the criteria for granting a stay under 21 C.F.R. § 10.35(e), and found that your request failed to meet the criteria.

96P-0087

PDN 1

draft policy statement, see 52 Fed. Reg. 36104 (Notice of Availability of the Draft FDA Policy for the Regulation of Computer Products), which was revised and reissued in draft in 1989 as the "FDA Policy for the Regulation of Computer Products 11/13/89 Draft" ("1989 Draft Policy").

In the 1989 Draft Policy, the agency stated its regulatory intentions regarding software products that meet the definition of medical devices, 21 U.S.C. § 321(h), and are not components, parts, or accessories of other articles which are themselves medical devices. FDA specified that such products would be subject to regulation as devices. Depending on its characteristics, a software device would be subject to one of several levels of regulatory control. 1989 Draft Policy at 2-3. FDA also stated that it would grant future exemptions from registration, listing, premarket notification, medical device reporting, and current good manufacturing practice requirements for certain products. However, any such exemptions would not apply to "manufacturers of computer hardware and software devices intended for use in blood banks." Id. at 3.

With regard to software devices intended for use in blood establishments, FDA initially focused regulation of blood establishment software at the user end, not at the software development stage. FDA provided guidance to blood establishments to help improve current Good Manufacturing Practices with regard to use and validation of software.<sup>2/</sup> However, a number of circumstances led FDA to determine that a regulatory scheme that focused only on the user end was inadequate to assure the quality of software used in blood establishments and inadequate to protect the public health.

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<sup>2</sup>The issuance of guidances in 1988 and 1989 by FDA's Center for Biologics Evaluation and Research ("CBER") to blood establishments regarding blood cGMPs applicable to computer software supplemented, rather than excluded, the policy expressed in the 1987 and 1989 draft documents directed at software manufacturers. While such software is a device subject to device cGMPs, it is also equipment used in a blood establishment and thereby subject to blood and drug cGMPs under the establishment's license and under the Public Health Service Act, 42 U.S.C. § 201 et seq., and the Federal Food, Drug, and Cosmetic Act. See, e.g., 21 U.S.C. § 351(a)(2)(B). The 1988 and 1989 CBER guidances were directed to manufacturers of blood and blood products, and were intended to provide general guidance to blood establishments with regard to procedures for ensuring the security and confidentiality of data, and for system documentation.

During establishment inspections, FDA investigators observed numerous problems with software, including a number of 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. Indeed, these observations revealed that unsuitable blood and blood components had in fact been released and distributed as a result of improperly designed software. Blood Products Advisory Committee Meeting Minutes, June 20, 1996 ("1996 BPAC") at 18. These observations resulted in warning letters and recalls of the unsuitable blood and blood components, as well as warning letters and recalls of the defective software itself. Further, as blood establishment software programs became increasingly complex, FDA investigators found that validation at the user end was proving impracticable, as well as insufficient to assure software performance. In addition, the then-chairman of the House subcommittee with oversight responsibilities over FDA called for increased regulation of software products used for medical purposes.<sup>3/</sup> Industry representatives also called for increased regulation, agreeing that such software should be regulated as a device, although opposing premarket submission requirements.<sup>4/</sup> In response to all of these circumstances, and after consideration of views expressed within the agency and by others, including industry representatives and congressional representatives (see, e.g., Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, July 28, 1993, Statement of David A. Kessler, M.D.), FDA determined that premarket regulation of blood establishment software should be implemented.

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<sup>3</sup>July 27, 1993 Memorandum by Chairman John D. Dingell to the Members of the House Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce.

<sup>4</sup>See, for example, November 1, 1990 letter from the Council of Community Blood Centers ("CCBC") to Gerald V. Quinnan, Jr., Acting Director of CBER; May 3, 1994 Health Industry Manufacturers' Association ("HIMA") Position Paper on FDA Regulation of Software Used in Blood Establishments. Since FDA issued its letter dated March 31, 1994, CCBC has written the agency twice to oppose regulation through premarket submissions for blood establishment software, once by letter dated May 31, 1994, and once by letter dated March 26, 1996. The March 26, 1996 letter was submitted in support of your petition to stay the March 31, 1996 deadline, and was, along with CCBC's other correspondence and the rest of the administrative record, considered in responding to your petition.

To that end, on March 31, 1994, the agency sent a letter to blood establishment software manufacturers reminding them that blood establishment software met the definition of a device and informing them that premarket submissions pursuant to section 510(k) of the Food, Drug, and Cosmetic Act ("FDC Act"), 21 U.S.C. § 360(k) ("510(k) notifications"), would be required for such software ("March 1994 letter").<sup>5/</sup> The March 1994 letter stated that such regulation was necessary to help assure the safety and effectiveness of such products and protect the blood supply.<sup>6/</sup> The letter described why blood establishment software meets the definition of a medical device under 21 U.S.C. § 321(h), delineated the device requirements applicable to blood establishment software, and requested that within one year, by March 31, 1995, manufacturers file their 510(k) notifications. After evaluating the concerns of affected software manufacturers and the impact of the requirement on blood establishments, the agency extended the date for receipt of 510(k) notifications another year, to March 31, 1996.<sup>7/</sup> The agency also advised blood establishments that they could request more time beyond March 31, 1996, to convert to systems for which the manufacturers had made a 510(k) notification.

Through guidance documents, public meetings, hearings, warning letters, and other communications, the agency has continued to explain to manufacturers how to comply with the statutory and regulatory requirements applicable to blood establishment software devices. CBER has conducted over 100 meetings and teleconferences with manufacturers, assisting firms in understanding what elements should be included in their 510(k) notifications and disseminating information related to the application of CGMPs to the design and development of blood establishment software.

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<sup>5</sup>As reflected in the Intercenter Agreement between the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health ("CDRH") (October 31, 1991) (Intercenter Agreement), CBER has the lead responsibility in regulating, under the Medical Device Authorities, medical devices, including software, used or intended for use in the collection, processing, storage, or administration of blood products, blood components, or analogous products. Intercenter Agreement § VI.

<sup>6</sup>The March 1994 letter was published in the Federal Register. 59 Fed. Reg. 44991 (Aug. 31, 1994).

<sup>7</sup>See 60 Fed. Reg. 51802 (Oct. 3, 1995) (publishing a letter dated Feb. 10, 1995 giving manufacturers the one year extension).

## II. Blood Establishment Software Is A Device.

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.

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) commands FDA to consider the intended use of the product. The intended use of a product determines its status as 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 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."); 1996 BPAC at 65-66 (blood establishments rely heavily on the data maintained on software systems; that reliance relates to the prevention of disease because it directly impacts the release of blood products.)

FDA has considered your contention that other equipment used to manufacture biologicals and pharmaceuticals may pose a risk to health if not properly designed, maintained, and operated. Petition at 5. However, as you also observe, that fact alone does not determine whether something is a medical device; what determines a product's status as a device is its intended use. Id. at 4. Toftness Radiation Detector, 731 F.2d at 1256. Indeed, the intended use of blood establishment software is a very important one. Moreover, its role is increasing in importance. 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.

1996 BPAC at 42. 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.<sup>2/</sup>

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<sup>2/</sup>Your suggestion that blood establishment software is somehow equivalent to automobile safety belts, Petition at 4, n.3, is similarly unpersuasive. FDA has determined that seat

Finally, contrary to your assertion, Petition at 4-5, this is not an unprecedented application of the agency's device authority. 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. 878.5070; see also, Ster-O-Lizer, 714 F. Supp. at 1164-65 & n.12 (upholding the agency's determination that a surgical instrument sterilizer is a device).

In sum, the agency's interpretation that blood establishment software is a medical device is entirely consistent with its approach to regulation of other products used in medical applications in blood establishments and elsewhere. That determination is entitled to deference. Community Nutrition, 476 U.S. at 981; see also CIBA, 412 U.S. at 643-44; Chevron, 467 U.S. at 844.

III. FDA Has Determined that Blood Establishment Current Good Manufacturing Practices Are Insufficient To Assure the Safety and Effectiveness of Blood Establishment Software; That Determination is Entitled to Deference.

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belts are not devices within the meaning of the FDC Act. Generally, injury preventive equipment is not "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" and is not "intended to affect the structure or any function of the body." 21 U.S.C. § 321(h). Moreover, because this decision involves FDA's scientific judgment, FDA's rejection of your comparison to an automobile seat belt is entitled to great deference. Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 654 (1973) ("threshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the court stays its hand"); Stauber v. Shalala, 895 F. Supp. 1178, 1189 (W.D. Wis. 1995) ("[W]hen a decision goes to the core of an agency's expertise, generally the court must defer to the agency's more-informed judgment."). See also Tri Bio Laboratories, Inc. v. United States, 836 F.2d 135, 142 (3d Cir. 1987), cert. denied, 488 U.S. 818 (1988) ("in evaluating scientific evidence in the drug field, the FDA possesses an expertise entitled to respectful consideration by th[e] court.")

You assert, Petition at 8-10, that software can be adequately regulated through the application of current Good Manufacturing Practice ("CGMPs") at blood establishments. See 21 C.F.R. Parts 210, 211, 640, and 606. This assertion fails to consider the historical failure of some blood establishments to assure the safety and effectiveness of software design. As described supra, at 2-3, inspections of blood establishments have revealed instances in which unsuitable blood and blood components have been released as a result of software design defects.

Because blood establishment software has become increasingly complex, validation by the end user is increasingly inadequate to identify and control software "glitches." Accordingly, in order to protect the public health, FDA has determined that it is important for FDA to deal directly with the people who design and develop blood establishment software through its review of 510(k) notifications. This kind of direct communication is crucial to the agency's ability to regulate the safety and effectiveness of blood establishment software products. Moreover, because the decision involves FDA's scientific judgment, FDA's determination is entitled to great deference. Bentex Pharmaceuticals, 412 U.S. at 654; Stauber, 895 F. Supp. at 1189; Tri Bio Laboratories, 836 F.2d at 142.

IV. In Developing Its Blood Establishment Software Policy, FDA Was In Compliance With the Notice and Comment Provisions of the APA.

You contend that the agency has not complied with provisions of the Administrative Procedure Act ("APA") in its regulation of blood establishment software as a medical device. Petition at 4-8. The agency rejects this contention. Since the agency has not promulgated a substantive rule, the APA requirement of notice and comment rule making for substantive rules is inapplicable.

A. FDA's Interpretation of the Statutory Provisions Governing 510(k) Notifications to Require Submissions by Blood Establishment Software Manufacturers Is Not a Substantive Rule Which Must Be Promulgated by Notice and Comment Rulemaking.

Under 5 U.S.C. § 551(4), a rule is "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency." As the D.C. Circuit noted many years ago, "[t]his broad definition obviously could be read

literally to encompass virtually any utterance by an agency, including statements of general policy." Pacific Gas & Elec. Co. v. Fed. Power Comm'n, 506 F.2d 33, 37 (D.C. Cir. 1974). The real issue is not whether the interpretation is a rule, but whether it is a substantive requirement rather than an interpretive rule or policy statement. Id. at 38; see also Alcaraz v. Block, 746 F.2d 593, 613 (9th Cir. 1984). Only substantive rules must be promulgated through notice-and-comment rulemaking. See 5 U.S.C. § 553.

In American Mining Congress v. Mine Safety & Health Admin., 995 F.2d 1106 (D.C. Cir. 1993), the court reviewed the legal status of Program Policy Letters issued by the Mine Safety and Health Administration that defined a regulatory term that, when applicable, triggered a reporting requirement. The court identified four criteria, any one of which, if met, meant the agency action was a substantive rule and required notice and comment rulemaking procedures:

(1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative [i.e., substantive] rule.

Id. at 1112.

The agency's interpretation of the 510(k) notification provisions meets none of the above criteria. The statute in and of itself provides sufficient basis for the action, and the letter did not add anything to that authority. See Clinical Reference Lab., Inc. v. Sullivan, 791 F. Supp. 1499, 1504 n.6. (D. Kan. 1992) ("The decision to initiate enforcement proceedings against CRL amounted only to a determination that [its] containers were subject to regulation under the FDCA, a determination the FDA was entitled to make without resort to judicial or administrative hearings") (citing CIBA Corp. v. Weinberger, 412 U.S. 640, 643-44 (1973)); National Pharmaceutical Alliance v. Henney, Civil Action No. 99-0394 (JR), 1991 U.S. Dist. LEXIS 5931, at \*9 (D.D.C. April 20, 1999) ("The statute on its face provides all the 'legislative basis' that is necessary for the agency's action.") The agency did not publish in the Code of Federal Regulations the interpretation

contained in the March 1994 letter<sup>9</sup>; nor did the agency invoke its rulemaking authority. Lastly, the agency's action does not amend, repudiate, or conflict with a prior substantive rule. See Shalala v. Guernsey Memorial Hosp., 514 U.S. 87, 100 (1995) (holding that notice and comment was not required for interpretive rule because it did not effect a substantive change in existing regulations); compare Jerri's Ceramic Arts, Inc. v. Consumer Prod. Safety Comm'n, 874 F.2d 205, 208 (4th Cir. 1989) (holding that an interpretive statement that amended a prior substantive rule required notice and comment). Accordingly, like the Program Policy Letters at issue in American Mining, FDA's interpretation does not have the "force of law" and is exempt from notice and comment.

Similarly, FDA's policy statements in this area are not substantive rules. Interpretive rules and general statements of policy share many of the same attributes, Pacific Gas & Electric, 506 F.2d at 37 n.14, and can be difficult to differentiate, see Professionals and Patients for Customized Care v. Shalala, 56 F.3d 592, 601-602 (finding that the challenged FDA rule could fit either definition). FDA's interpretation has both the characteristic of an interpretive rule in that it reiterated the agency's longstanding view that software used in the manufacturing of blood and blood products meets the definition of a device, and that of a general statement of policy in that it announced the agency's policy to require 510(k) notifications in the future for such software. However, whether FDA's policy regarding blood establishment software is characterized as an interpretive rule or as a policy statement, it is exempt from the APA's notice and comment requirement. The agency's March 1994 announcement neither has the "force of law" that turns an interpretive rule into a substantive rule, American Mining Congress, 995 F.2d at 1109 (citing National Latino Media Coalition, 816 F.2d at 787-788), nor limits the discretion of agency decisionmakers so as to turn a policy statement into a binding rule of law. Community Nutrition, 818 F.2d at 946-48.

Finally, as interpretive rules and statements of policy, FDA's interpretations of the applicability of device law to blood establishment computer software are specifically exempted from notice and comment rulemaking under the APA. 5 U.S.C.

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<sup>9</sup>In any event, the publication-in-the-CFR criterion is only slight evidence of agency intent. See Health Ins. Ass'n. of America v. Shalala, 23 F.3d 412, 423 (D.C. Cir. 1994), cert. denied, 513 U.S. 1147 (1995) (CFR publication as no more than a "snippet" of evidence of agency intent).

§ 553(b)(A). The § 553(b)(A) exemptions for interpretive rules and policy statements "accommodate situations where the policies promoted by public participation in rulemaking are outweighed by the countervailing considerations of effectiveness, efficiency, expedition and reduction in expense." Guardian Fed. Savings and Loan Ass'n v. Federal Savings and Loan Ins. Corp., 589 F.2d 658, 662 (D.C. Cir. 1978). "If the mere delegation of rule-making authority meant all subsequent agency determinations were legislative, and had to meet the notice and comment requirements of the APA, agency functioning would be hamstrung." Metropolitan School District of Wayne Township v. Davila, 969 F.2d 485, 492 (7th Cir. 1992), cert. denied, 507 U.S. 949 (1993).

B. FDA Has Not Changed A Settled Policy in its Regulation of Blood Establishment Software.

Your argument rests upon your assertion that "[b]oth the Agency and the industry have until now understood blood establishment software to be outside the definition of a medical device." Petition at 5-6. Building upon this premise, you assert that the March 1994 letter represented "a fundamental change in Agency policy and statutory interpretation." Petition at 6. However, FDA has long communicated its view that software that falls within the four corners of the statutory definition of a device, is, indeed, a device, and FDA has long communicated its intent to regulate blood establishment software with appropriate consideration for the significant role of blood establishment software in protecting the public health.

The agency's draft policy, originally made available to the public in 1987, states that computer products that meet the definition of a device under the FDC Act are subject to regulation as medical devices. 52 Fed. Reg. 36104. Two years later, the 1989 Draft Policy reiterated this position, and also put blood establishment software manufacturers on notice that the agency did not foresee including their products in any future exemptions from the statutory or regulatory requirements for devices. 1989 Draft Policy at 1, 3.

By excluding blood establishment software from the ambit of 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.<sup>10/</sup> In 1993, before the Oversight and Investigation Subcommittee 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 Investigation, Committee on Energy and Commerce (July 28, 1993).<sup>11/</sup> In the March 1994 letter, FDA announced its intention to regulate blood establishment software by requiring compliance 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. Moreover, from even before 1987, up to the present, the agency has informed the public, through other guidance documents, public meetings, Warning Letters, and other formal and informal communications, that computer software that meets the definition of a device would be regulated with the degree of regulatory control necessary to assure the safety and effectiveness of the device.

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<sup>10</sup>When 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.

<sup>11</sup>In 1993, the Energy and Commerce Committee's Subcommittee on Oversight and Investigations encouraged the agency to pursue regulation of blood establishment software as a means of further ensuring the safety of the public health by preventing distribution of unsuitable blood products. In light of the congressional scrutiny FDA's regulation of blood establishment software has received, your suggestion that FDA's policy with regard to blood establishment software manufacturers is somehow contrary to the will of Congress is puzzling. Petition at 12-13.

In view of the consistent statements that FDA has made on this subject, FDA does not accept your contention that FDA "presented no rationale" for its approach to regulation of blood establishment software. Petition at 7. Equally unavailing is your suggestion that FDA did not provide a reasoned analysis for its action. FDA explained its thinking and its actions from the outset.

In any event, an explanation of agency reasoning is required only when an agency changes a "settled" policy or interpretation. Motor Vehicles Mfrs. Ass'n v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29, 41-43 (1983). See Chen Zhou Chai v. Carroll, 48 F.3d 1331, 1341 (4th Cir. 1995) (holding that the State Farm requirement for reasoned analysis only applies to changes in substantive rules, not to amendments of interpretive rules or general statements of policy). See also Syncor Internat'l Corp. V. Shalala, 127 F.3d 90 (D.C. Cir. 1997) (notice and comment rulemaking required for agency's decision to alter previous decision; the later decision was not an interpretive rule because it did not "interpret" statutory language; government did not argue that the decision was a policy statement.)

Here, there has been no change in course. The agency's interpretation did not change; its regulatory approach evolved as the nature of the regulated product, blood establishment software, evolved. Rather than depart from a "settled" policy, FDA responded to the fast paced evolution of blood establishment software in a consistent and communicative manner. The agency provided its rationale in the letters to industry, the subsequent Federal Register notices, and ensuing communications such as Talk Paper 94-21, guidance documents, Warning Letters, and meetings with industry.

Furthermore, although the agency did not begin affirmatively calling for 510(k) notifications for blood establishment software products until March 1994, FDA made no abrupt or unforeseeable change in regulatory approach. As discussed above, for at least the past twelve years, the agency has communicated to the public that it considers software that meets the definition of a medical device to fall within the device provisions of the FDC Act. The agency's determination that 510(k) notifications are necessary to assure the safety and effectiveness of blood establishment software devices, developed

over a number of years.<sup>12/</sup> The policy reflected agency concerns about the impact on public health and safety of such products. It is incorrect to characterize the agency's call for 510(k) notifications for blood establishment software as a "sudden decision." Petition at 6.

V. Manufacturers Can Comply With The Requirements Of The FDC Act Applicable To Devices Without Undue Burden.

You assert that "[s]witching from existing software systems to approved software systems would cause massive disruptions in the operations of blood establishments." Petition at 9, n.11. However, you present no evidence to support that assertion.

Nor has FDA discovered such disruption during the five years since the March 1994 letter issued. As discussed above, FDA extended by one year the initial March 31, 1995 deadline for filing 510(k) notifications, in response to concerns raised by the blood industry. The extra year was intended to help software manufacturers and blood establishments work together to complete 510(k) notifications for software products, thereby minimizing any impact on blood establishment operations. In addition, by guidance memorandum dated November 13, 1995, CBER advised blood establishments that if they would be unable to convert by March 31, 1996 to systems for which manufacturers had made 510(k) notifications, they could request an extension, giving the reasons necessitating the extension and proposing an alternative timetable for conversion. CBER has evaluated such requests from blood establishments on a case-by-case basis, and has granted reasonable requests for additional time. Since March 1994, many blood establishment software manufacturers have achieved compliance with 510(k) notification requirements.<sup>13/</sup>

On the other hand, the quality of initial 510(k) notification submissions confirmed FDA's view that the notifications were necessary to assure the safety and effectiveness of the devices. Most of the initial 510(k) notifications revealed serious problems in the design and

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<sup>12</sup>We have determined that, in order to assure the development of quality medical devices, quality must be built in at the design stage of software development. FDA rejected your suggestion that "regulation of software systems used in bloodbank management is more efficiently carried out at the level of the individual blood establishment." Petition at 9.

<sup>13</sup>A listing of cleared 510(k) notifications is available on the FDA website at <http://www.fda.gov/cber/products/510ksoft.htm>.

development of blood establishment software, such as the lack of detailed design specifications, hazard analysis, or verification and validation testing, and missing or nonexistent documentation of some or all of those critical elements. Such fundamental and pervasive problems, especially in such safety-critical devices, cannot effectively be addressed at the user end.

You claim that the agency has inadequate resources and that CBER has inadequate expertise to review the 510(k) notifications in a timely manner. Petition at 10. With regard to resources, it should be noted that, as of this date, CBER has already reviewed and cleared 31 510(k) notifications. As for expertise, CBER employees are well trained in this area, and in any event obtain CDRH support for collaborative reviews when necessary. For consistency of review, CBER has developed, in collaboration with CDRH and the FDA Office of Regulatory Affairs, guidance for reviewers of blood establishment software products. FDA has made this guidance available to the public. See 62 Fed. Reg. 1767 (Jan. 13, 1997).

Moreover, FDA continues to search for more efficient ways to assure the safety and effectiveness of blood establishment software. At the June 20, 1998 Blood Products Advisory Committee Meeting, in a public session, FDA advised the advisory committee of its proposal to classify blood establishment software as a Class II device subject to special controls, and to couple the use of special controls with a new 510(k) paradigm, which would allow FDA to shorten review times. Blood Products Advisory Committee Meeting Minutes, June 20, 1998 ("1998 BPAC") at 27. FDA made this proposal with the support and participation of CDRH personnel. See 1998 BPAC at 46-72.

Your suggestion that CBER is somehow acting in a vacuum, without consulting with other components of the agency is incorrect. The agency rejects your suggestion that it would be "prudent" for FDA to 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. Citizen Petition at 11. Your suggestion 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). The 1989 Draft Policy itself announced that the level of regulation of software devices would vary depending on the characteristics of the device. 1989 Draft Policy at 2.

You also claim that the cost of complying with the agency's call for 510(k) notifications would be prohibitive for most software manufacturers, which tend to be small companies. Petition at 11. Once again, you present no evidence to support that assertion. And once again, the agency has no evidence that the cost of compliance is prohibitive. When it issued the March, 1994 letter, the agency anticipated that manufacturers who had been following industry standards for good software development practices would have documentation for 510(k) notifications readily available, and would not find the 510(k) notification process unduly burdensome. In order to assist manufacturers with their 510(k) notifications, FDA prepared and made available to manufacturers the reviewer guidance discussed supra at 17. From the very beginning, FDA has provided manufacturers with guidance on how to comply with the statutory requirements and has demonstrated a willingness to assist manufacturers in coming into compliance. See, e.g., 1989 Draft Policy at 1 ("Manufacturers . . . are encouraged to contact FDA with questions they may have" [giving a telephone number for questions regarding blood establishment software products]); March 1994 letter reprinted in 59 Fed. Reg. 44991 (Aug. 31, 1994) ("If you have questions about the content or format of a premarket submission once you have reviewed our guidance, CBER staff are available to help answer such questions"); February 10, 1995 Letter to Blood Establishment Computer Software Manufacturers, reprinted in 60 Fed. Reg. 51802 (Oct. 3, 1995) ("To effectively implement this important and complex regulatory program, the agency intends to work with industry to clarify the expectations concerning premarket submissions through issuance of guidance. We also plan to have a continuing dialogue with affected establishments and industry"). See also 1996 BPAC at 70-93 and 1998 BPAC at 28-46, 74-79 (open public meetings where industry and patient representatives discussed blood establishment software regulation issues); 62 Fed. Reg. 1767 (Jan. 13, 1997) (announcing availability of "Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software").

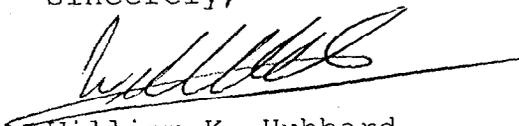
Finally, FDA rejects your suggestion, Petition at 11, that FDA should have conducted a regulatory flexibility analysis here. See 5 U.S.C. § 603. This requirement applies only to notice and comment rulemaking. See 5 U.S.C. § 603(a) (regulatory flexibility analysis required "[w]henver an agency is required" under the APA to use notice and comment rulemaking procedures); 5 U.S.C. § 601(2) (defining the term "rule" for purposes of regulatory flexibility requirements to exclude rules for which notice and comment is not proposed or provided). FDA has not used notice and comment rulemaking procedures here; nor

was it required to do so (see discussion supra at 8-11). Accordingly, no regulatory flexibility analysis was required here.

## VI. Conclusion

For the reasons stated above, your petition for a stay of the deadline for 510(k) notifications for blood establishment software is denied. The agency continues to expect that manufacturers of blood establishment software will have filed 510(k) notifications by March 31, 1996, in accordance with the March 31, 1994 and February 10, 1995 letters and the August 31, 1994 (59 Fed. Reg. 44991) and October 3, 1995 (60 Fed. Reg. 51802) Federal Register notices.

Sincerely,



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