



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG - 7 2000

Janet Trunzo
Associate Vice President
Technology and Regulatory Affairs
Health Industry Manufacturers Association
1220 G Street, N.W., Suite 400
Washington, DC 20005

re: Docket No. 99P-2725

Dear Ms. Trunzo:

This letter is in response to the Health Industry Manufacturer's Association's (HIMA) Citizen Petition of August 9, 1999. In that petition, you argued that use by FDA's Center for Devices and Radiological Health (CDRH) of nonpublic data contained in premarket approval applications (PMAs) approved before February 19, 1998, in reclassifying lithotripters is an illegal, retroactive application of section 216 of the Food and Drug Administration Modernization Act of 1997 (FDAMA).¹ Your petition requested that the Commissioner of the FDA issue an order prohibiting application of section 216 to any such data. In order to fully evaluate your petition, I consulted with FDA's Office of Chief Counsel. The legal research and conclusions of that office are incorporated in this response. For the reasons discussed below, your petition is granted in part and denied in part.

I. Section 216 of FDAMA is the third of three increasingly permissive provisions governing use of data from PMAs.

As you discuss in your petition, section 216 of FDAMA established the six-year rule, which provides in part:

[a]ny information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) (including information from clinical or preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition and other trade secrets) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in-

- (i) approving another device;
- (ii) determining whether a product development protocol has been completed, under section 515 for another device;
- (iii) establishing a performance standard or special control under this Act; or
- (iv) classifying or reclassifying another device under section 513 or subsection (1)(2).

¹ P.L. 105-115, 111 Stat.2296 (1997).

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This provision replaced the previous section 520(h)(4) of the Food, Drug, and Cosmetic Act (FDCA), which was added by the Safe Medical Devices Act of 1990 (SMDA) and established the four-of-a-kind rule for use of data in PMA applications. Under the four-of-a-kind rule, the agency could use data contained in any filed PMA application one year after FDA had approved the fourth device of a kind.² The four-of-a-kind provision also contained detailed rules for its application to data in applications approved before SMDA's effective date. The SMDA provision replaced section 520(h)(3), which was enacted with the Medical Device Amendments of 1976 (MDA).³ Under the MDA rule, the agency could not use data in one PMA to establish the safety or effectiveness of any device other than the one for which the data was submitted.

Congress provided little explanation of the 6-year data use provision in FDAMA's legislative history. The legislative histories of the MDA and SMDA, however, each contain discussions relevant to the use of data provisions in those laws. See S. Rept. No. 513, 101st Cong., 2d Sess. 24 - 26 (1990); H. Rept. 808, 101st Cong., 2d Sess. 27 - 28 (1990); H. Rept. No. 853, 94th Cong., 1st Sess. 50 (1976). These discussions provide a general insight: namely, that although legal rules facilitating market entry can harm fledgling industries, in strong, established markets,

² The use of data provision enacted with the SMDA provided:

(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c), including clinical and preclinical tests or studies, but excluding descriptions of methods of manufacture and product composition, that demonstrates the safety and effectiveness of a device shall be available 1 year after the original application for the fourth devices of a kind has been approved by the Secretary, for use by the Secretary in approving devices, or determining whether a product development protocol has been completed, under section 515, establishing a performance standard under section 514, and reclassifying devices under subsections (c) and (f) of section 513, and subsection (1)(2). ...

(B) The Secretary, contemporaneously with the approval of the fourth device of a kind, shall publish an order in the Federal Register identifying the four devices of a kind that have been approved under section 515 and the date on which the data contained in the premarket approval applications will be available to the Secretary for use, as described in subparagraph (A).

(C) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the regulatory action described in subparagraph (A).

(D)(i) This paragraph shall become effective—

(I) on November 15, 1990, for devices for which four devices of a kind were approved on or before December 31, 1987, and

(II) on November 15, 1991, for devices not described in subclause (I).

(ii) For each device described in clause (i)(I) the Secretary shall publish a notice in the Federal Register setting forth the date, which shall not be earlier than 1 year after the date of the notice, that the data identified in subparagraph (A) shall be available for the use of the Secretary.

(E)(i) Except as provided in clause (ii), the approval date of a device, for purposes of this paragraph, shall be the date of the letter of the Secretary to the applicant approving a device under section 515 and permitting the applicant to commercially distribute the device.

(ii) For each device described in subparagraph (D)(i)(II) for which the original application for a fourth device of a kind is approved by the Secretary before November 1, 1991, the approval date of the fourth device of a kind shall be deemed to be November 15, 1991.

(F) Any challenge to an order under subparagraph (B) shall be made not later than 30 days after the date of the Federal Register notice referred to in such subparagraph.

³ Section 520(h)(3), enacted with the MDA, provided:

Any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) [detailed summaries of safety and effectiveness made publicly available] may not be used to establish the safety or effectiveness of another device for purposes of this Act by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section.

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such rules will generally benefit both industry and consumers. Just as in 1990 the device industry was stronger than it had been in 1976, in 1997, the industry was stronger still, see H. Rept. 307, 105th Cong., 1st Sess. 14 (1997), and, one can infer, better able to prosper without the aid of anticompetitive rules.

The agency never applied the four-of-a-kind provision; however, FDA used its authority under the new section 520(h)(4) in its proposed reclassification of electric shock wave lithotripters for fragmenting kidney and ureteral calculi from class III to class II. See 64 Federal Register 5987 (February 8, 1999). Although the Agency believes it had sufficient data to reclassify lithotripters without using data from PMAs approved more than six years ago, the additional data from five PMAs approved in 1991 provides further support for the reclassification.

II. The Agency Will Apply Section 216 to Free Data Contained in PMAs Approved After SMDA's Effectiveness Date.

Your petition challenges any use by the agency of data contained in PMAs approved before section 216 of FDAMA took effect. Balancing the notice and fairness concerns of earlier PMA sponsors with the desire of the agency and later sponsors to have access to data, FDA has concluded that it will apply the six-year rule only to data contained in PMAs approved after November 28, 1990. The relief requested in your petition, then, is granted concerning PMAs approved before SMDA's effectiveness date.

The agency's proposed reclassification of lithotripters is its only application of section 520(h)(4); consistent with FDA's approach to the provision, the proposal relies upon data contained in PMAs approved after SMDA. With respect to such PMAs, your petition is denied. The remainder of this response will address your challenges to FDA's use of data in such PMAs, particularly as they apply to the agency's recent proposed reclassification of lithotripters.

III. FDA's Use of PMA Data from PMAs Approved Before FDAMA is a Permissible Agency Interpretation of Section 520(h)(4).

Your petition relies upon the presumption against retroactive legislation affirmed in recent Supreme Court precedent to assert that the agency's proposed reclassification of lithotripters, and any use by the agency of data contained in PMAs approved before February 19, 1998, is retroactive and illegal. (Petition at pp. 4 - 5, discussing Landgraf v. USI Film Products, 114 S.Ct. 1483 (1994)). As your petition notes, one district court has ruled that Congress did not intend FDAMA to apply retroactively, United States v. 302 Cases, 25 F. Supp. 2d. 1358, 1363 (M.D.Fla. 1998). The petition, however, only briefly discusses what constitutes retroactivity. (Petition at p. 5). Under Landgraf and other relevant decisions, FDA's reclassification of lithotripters is not retroactive and does not trigger the presumption of invalidity.

A. Section 520(h)(4), when Applied to Data in PMAs Approved Six Years Earlier, in Regulatory Actions Taken After February 19, 1998, Operates Prospectively.

1. FDA's Reclassification of Lithotripters Does Not Upset Legally Protected Interests.

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Landgraf held that a plaintiff suing for employment discrimination based on acts occurring in the mid-1980s could not rely upon a cause of action and damage provision that went into effect in 1991, during the pendency of her appeal. The Court affirmed a longstanding and flexible definition of retroactive law as law that "would impair rights a party possessed when he acted, increase a party's liability for past conduct, or impose new duties with respect to transactions already completed," id. at 1505.⁴ The Court did not attempt to set out bright line rules, but noted that "considerations of fair notice, reasonable reliance, and settled expectations offer sound guidance" in determining whether a statute has a retroactive effect, id. at 1499; see also Martin v. Hadix, 119 S. Ct. 1998 (retroactivity inquiry requires "common sense, functional judgment"). These considerations support the propriety of FDA's use of section 520(h)(4) in reclassifying lithotripters.

Beginning November 28, 1990, when Congress enacted the SMDA, manufacturers of lithotripters, and all other medical devices approved after that date, received notice that the agency could use data contained in their approved PMA applications following approval of the third additional PMA for a device of the same kind, in accordance with the rules of the four-of-a-kind provision.⁵ Data contained in the lithotripter applications used by FDA in its recent reclassification has been available for use by the agency since at least late 1992. Sponsors of

⁴ The Landgraf opinion uses an analysis that is primarily functional; however, it could be read to incorporate elements of a categorical approach. The Landgraf Court wrote that laws that operate procedurally or provide a new remedy to an existing cause of action may be applied to pending litigation, but substantive laws that lack an express statement of retroactive effect are subject to the presumption against their retroactive application. In Hughes Aircraft Co. v. Schumer, however, the Court explained that the discussion in Landgraf did not suggest a different rule for different categories of statutes, only that some statutes were less likely to meet the functional criteria that define a retroactive effect, 117 S. Ct. 1871, 1878 (1997).

Another categorical approach is to characterize the application as one of primary or secondary retroactivity see, e.g., Hughes v. 1871 (distinguishing laws that affect secondary conduct from those that affect primary conduct); Kaiser Aluminum & Chemical Corp. v. Bonjorno, 110 S. Ct. 1570, 1592 (1990) (dissenting opinion) (a law that operates with primary retroactivity changes the past consequences of past events). Were FDA to use section 520(h)(4) to reopen, for example, PMA approvals the agency had issued before FDAMA's effective date, the agency would be using new authority to undo transactions completed in the past. Such an application is retroactive under any legal definition of id. at 1591 ("true retroaction . . . involves the application of a change in law to overturn [an] adjudication of rights that has already become final"). The agency's application of section 520(h)(4) in the reclassification of lithotripters, on the other hand, took place after FDAMA's effective date. In late 1998 and 1999, the agency used authority it gained in February 1998 to rely upon certain transactions that occurred in the early 1990's. In case law and commentary, when a provision of law affects the future consequences of past acts, but operates prospectively on the primary behavior the provision governs, the effect of the statute is sometimes described as one of "secondary retroactivity" of Landgraf at 1524 (concurring opinion) (retroactivity of a law should be decided by effect of law on "the relevant activity that the rule regulates").

The Court in Landgraf, in dicta, affirms the validity of several applications of law having a secondarily retroactive effect, Landgraf at 1499 n.24; the application of damage provisions rejected in Landgraf, however, would have changed only the future effect the discriminatory behavior. Under Landgraf, then, the categorization of a law as primarily or secondarily retroactive, like other formal approaches, is not decisive.

⁵ The four-of-kind rule, like the six-year rule, ties use of data to the date of PMA approval, rather than the date of submission. Operation of either rule would free some data in PMAs submitted under the protective rule enacted in the MDA but approved after SMDA. Sponsors of those PMAs, however, were free to withdraw their submissions to preclude agency use of their data for other purposes. The operation of use of data rule before approval of these PMAs, then, does not "change the legal consequences" of their submission. See Martin v. Hadix, 119 S. Ct. 1998, 2007 (1999).

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those applications have not argued that FDA's actions have unsettled their protected expectations or deprived them of property interests. Such challenge would be baseless, as the two use-of-data provisions create the same expectation that data submitted by these sponsors could be made available.

Although manufacturers may have anticipated that the SMDA rule would result in an extended or permanent period of protection for data contained in the applications of devices unlikely to be the subject of four or more applications, SMDA created no settled expectation of data protection on which manufacturers of such devices could reasonably rely. Medical advances, new technologies, and a variety of other market forces will affect the number of PMAs the agency receives for a device. At best, these factors follow trends that informed individuals can predict with imperfect accuracy. The uncertainty of these factors preclude any argument that use of data under 520(h)(4) "would impair a right" created by the four-of-a-kind rule. Compare Ruckelshaus v. Monsanto, 104 S. Ct. 2862, 2874 - 2878 (1984) (distinguishing, for purposes of the Takings Clause, protected expectations created by express statutory promise from "unilateral" or "abstract" projections).

2. Submission and Approval of PMAs before February 19, 1998, Are Antecedent Facts on Which FDA May Properly Rely in Applying 520(h)(4).

When a change in law does not upset a protected right, expectation, or interest, that the law "draws upon antecedent facts for its operation" does not make it retroactive, Landgraf, at 1499 n.24. As the Landgraf Court noted, "even uncontroversially prospective statutes may unsettle expectations and impose burdens on past conduct: a new property tax or zoning regulation may upset the reasonable expectations that prompted those affected to acquire property; a new law banning gambling harms the person who had begun to construct a casino before the law's enactment or spent his life learning to count cards." Id.

FDA's reclassification of lithotripters is analogous to these "uncontroversially prospective" applications of law. In an action commenced in February, 1999, the agency used authority from a statute enacted in 1997 that became effective on February 19, 1998. Although FDA's action drew upon approvals under a different legal rule that engendered somewhat different expectations, this ancillary effect of FDA's application of the new rule does not invalidate the primarily prospective operation of the law in facilitating certain post-FDAMA agency actions. See Landgraf at 1499 ("[t]he conclusion that a particular rule operates "retroactively" comes at the end of a process of judgment concerning the nature and extent of the change in the law and the degree of connection between the operation of the new rule and a relevant past event.")

Your petition also argues that FDAMA's delayed effective date indicates a Congressional intent that the law receive prospective application only, and cites several cases inferring prospective application from delayed effectiveness. (Petition at 6 - 7). Because FDA's use of section 520(h)(4) to free data contained in lithotripter PMAs submitted in the early 1990s does not have a retroactive effect, FDAMA's delayed effective date is not relevant to the validity of FDA's

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action. Moreover, section 501 was added late in FDAMA's passage, and has no legislative history.⁶

B. FDA's Interpretation of Section 520(h)(4) is Reasonable.

Given no presumption against retroactivity applies because FDA's application of section 520(h)(4) has only a prospective effect, even assuming other plausible interpretations of the section exist, FDA's reasonable interpretation is entitled to deference. Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 104 S. Ct. 28 (1984); cf. Your Home Visiting Nursing Services v. Shalala, 119 S. Ct. 930, 934 (1999); Skidmore v. Swift & Co., 65 S. Ct. 161 (1944) (interpretive rules by administering agency receive degree of deference). The agency's construction of 520(h)(4) to free data contained in PMAs submitted after SMDA is a conscientious attempt to balance the notice and fairness concerns of some sectors of the device industry with efficiency and access concerns of the Agency and those manufacturers that may benefit from application of the use-of-data rule. The Agency has struck this balance in a way that is consistent with the statutory language and effectuates the legislative purpose of the provision. Enhanced reliance on data previously reviewed by FDA is also consistent with other provisions of FDAMA that encourage the "least burdensome" pathways to product development and approval.

In contrast, the construction urged by HIMA is inconsistent with the main effect of the provision, which is to expand access to PMA data by making it available regardless of how many submissions the agency receives for a particular device. Your petition argues that section 520(h)(4) frees only data from PMAs approved after FDAMA's effective date, and use by the Agency of data from any other PMA would be retroactive and illegal. This construction would not only deny the Agency use of its new authority for 6 years, but would permanently deprive the agency of access to data in any PMA approved before February 19, 1998, including data previously freed by the four-of-a-kind rule. The construction urged by HIMA, then, would

⁶ "Section 501 — Effective Date" first appeared in the Senate bill on November 13, 1997. See 143 Cong. Rec. S12616. The provision that appears in FDAMA reads:

Except as otherwise provided in this Act, this Act and the amendments made by this Act, other than the provisions of and the amendments made by sections 111, 121, 125, and 307, shall take effect 90 days after the enactment of this Act.

Several provisions of FDAMA, particularly in Title I, relating to the regulation of drugs, contain their own effective dates, including three of the four sections excluded from the ninety day effective date in section 501. Sections 130 and 307 expressly apply to matters pending before the agency, raising the inference that other provisions of FDAMA apply only to matters initiated after the effective date of the relevant provision. Other provisions of FDAMA become effective before the default effective date of ninety days after enactment, after that date, before FDAMA's passage, or create rules concerning effectiveness designed to preserve certain pieces of legislation while preempting others, see section 412.

Because section 216 of FDAMA does not set out its own rules for taking effect, under section 501, the six-year provision took effect on February 19, 1998. A statute that takes effect on a designated date after enactment of the statute may affect the consequences of actions initiated before that date in the same way any statute may relate to antecedent events without running afoul of retroactivity doctrine, see Kaiser, 110 S. Ct. at 1590 - 91 (dissenting opinion) (distinguishing effective date provisions from Congressional directives on retroactive effect). The most apparent meaning of section 501, then, does not render FDA's application of section 216 illegal. Given the redundancy of the first dependent clause of section 501 with the reference to sections 121, 125, and 307, the failure to state 111's effective date in either section 111 or section 501, and the superfluous references to the default effective date in sections 211 and 212, the value of trying to glean deeper meaning from section 501 of FDAMA is doubtful.

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unsettle expectations by depriving later PMA applicants, and the FDA, of the benefit of data the SMDA rule made available in the early 1990's.

In summary, section 216 of FDAMA permits the agency, in conducting certain regulatory actions, to use data in PMAs approved at least six years earlier. FDA may use this authority to free data contained in PMAs approved before FDAMA's effective date, although the agency is adopting an interpretation of the new legal rule to free only data in PMAs approved after November 28, 1990. This interpretation will result in the provision having a prospective effect only, so the provision will not trigger the presumption against retroactive law. The interpretation is a reasonable reading of an unclear provision, and merits deference.

As you know, FDA concluded that there was sufficient information to downclassify lithotriptors without relying on the data made available to the agency under section 216. The use of that data from other PMAs to provide additional support for the downclassification, however, is an appropriate application of the new provision in light of the analysis presented above. CDRH reviews numerous PMAs and requests for reclassification. Applying section 216 in the manner described in this response will protect the legitimate proprietary expectations of certain manufacturers while ensuring that other sponsors are able to get safe and effective products to consumers as efficiently as possible.

For the reasons above, your petition is granted in part and denied in part. In light of the concerns raised by your petition, CDRH has issued guidance that will inform industry of the agency's interpretation of this provision and its application to ongoing reviews. We are enclosing a copy of that guidance with this response.

Sincerely yours,



Linda S. Kahan
Deputy Director for
Regulation and Policy
Center for Devices and
Radiological Health

Enclosure

Guidance for Industry and for FDA Reviewers

Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997

Draft released for comment on [release date as stated in FR Notice]



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

Office of Device Evaluation

Guidance¹ on Section 216 of the Food and Drug Modernization Act of 1997

I. INTRODUCTION

This document provides guidance for industry and for FDA reviewers on the Food and Drug Administration's (FDA) interpretation of section 216 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The document describes how the Center for Devices and Radiological Health (CDRH) will apply the new provision and explains why FDA, through CDRH, has adopted this approach.

II. BACKGROUND

Section 216 of FDAMA establishes the six-year rule, under which:

(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) (including information from clinical or preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition and other trade secrets) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in-

- (i) approving another device;
- (ii) determining whether a product development protocol has been completed under section 515 for another device;
- (iii) establishing a performance standard or special control under this Act; or
- (iv) classifying or reclassifying another device under section 513 or subsection (1)(2).

(B) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the agency actions described in subparagraph (A).

This provision replaced the previous section 520(h)(4) of the Food, Drug, and Cosmetic Act (FDCA), which was added by the Safe Medical Devices Act of 1990 (SMDA) and established the four-of-a-kind rule for use of data in PMA applications. Under the four-of-a-kind rule, the agency could use data contained in any filed PMA application 1 year after FDA had approved

¹ This guidance document represents the Agency's current thinking on the interpretation of section 216 of the Food and Drug Administration Modernization Act of 1997. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Preface

Public Comment

Until [date 90 days from release date], comments and suggestions regarding this document should be submitted to Docket No. [fill in number], Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Such comments will be considered when determining whether to amend the current guidance.

After [date 90 days from release date], comments and suggestions may be submitted at any time for Agency consideration to: [name of individual or originating organization, mail code, and address]. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Robert R. Gatling, Jr. at 301-594-1190 or by electronic mail at RRG@CDRH.FDA.GOV.

Additional Copies:

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the fourth device of a kind.² The four-of-a-kind provision also contained detailed rules for its application to data in applications approved before SMDA's effective date. The SMDA provision replaced section 520(h)(3), which was enacted with the Medical Device Amendments of 1976 (MDA).³ Under the MDA rule, the agency could not use data in one PMA to establish the safety or effectiveness of any device other than the one for which the data was submitted.

² The use of data provision enacted with the SMDA provided:

Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c), including clinical and preclinical tests or studies, but excluding descriptions of methods of manufacture and product composition, that demonstrates the safety and effectiveness of a devices shall be available 1 year after the original application for the fourth devices of a kind has been approved by the Secretary, for use by the Secretary in approving devices, or determining whether a product development protocol has been completed, under section 515, establishing a performance standard under section 514, and reclassifying devices under subsections (e) and (f) of section 513, and subsection (1)(2). . . .

(B) The Secretary, contemporaneously with the approval of the fourth device of a kind, shall publish an order in the Federal Register identifying the four devices of a kind that have been approved under section 515 and the date on which the data contained in the premarket approval applications will be available to the Secretary for use, as described in subparagraph (A).

(C) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the regulatory action described in subparagraph (A).

(D) (i) This paragraph shall become effective--

(I) on November 15, 1990, for devices for which four devices of a kind were approved on or before December 31, 1987, and

(II) on November 15, 1991, for devices not described in subclause (I).

(ii) For each device described in clause (i)(I) the Secretary shall publish a notice in the Federal Register setting forth the date, which shall not be earlier than 1 year after the date of the notice, that the data identified in subparagraph (A) shall be available for the use of the Secretary.

(E) (i) Except as provided in clause (ii), the approval date of a device, for purposes of this paragraph, shall be the date of the letter of the Secretary to the applicant approving a device under section 515 and permitting the applicant to commercially distribute the device.

(ii) For each devices described in subparagraph(D) (i) (II) for which the original application for a fourth device of a kind is approved by the Secretary before November 1, 1991, the approval date of the fourth device of a kind shall be deemed to be November 15, 1991.

(F) Any challenge to an order under subparagraph (B) shall be made not later than 30 days after the date of the Federal Register notice referred to in such subparagraph.

³ Section 520(h)(3), enacted with the MDA, provided:

Congress provided little explanation of the 6-year data use provision in FDAMA's legislative history. The legislative histories of the MDA and SMDA, however, each contain discussions relevant to the use of data provisions in those laws. See S. Rept. No. 513, 101st Cong., 2d Sess. 24 - 26 (1990); H. Rept. 808, 101st Cong., 2nd Sess. 27 - 28 (1990); H. Rept. No. 853, 94th Cong., 1st Sess. 50 (1976). These discussions provide a general insight: namely, that although legal rules facilitating market entry can harm fledgling industries, in strong, established markets, such rules will generally benefit both industry and consumers. In 1990, the device industry was stronger than it had been in 1976. By 1997, the industry was even stronger, see H. Rept. 307, 105th Cong., 1st Sess. 14 (1997) and better able to prosper without the aid of anti-competitive rules.

The Center never applied the SMDA four-of-a-kind provision; however, CDRH used its new FDAMA authority in its proposed reclassification of extracorporeal shock wave lithotriptors for fragmenting kidney and ureteral calculi from class III to class II. See 64 Federal Register 5987 (February 8, 1999). Although CDRH believes it had sufficient data to reclassify lithotriptors without using its authority under the new section 520(h)(4), this authority, by freeing data in five PMAs approved in 1991, provides additional support for the reclassification.

Before and since CDRH published its proposed reclassification, the Center received several letters from associations of medical device manufacturers advocating particular constructions of section 216. One association believed the provision allowed CDRH to rely on data in PMAs approved any time 6 or more years have passed; one association, which submitted a citizen's petition (see Docket Number 99P2725) outlining its views, believed the provision allowed CDRH to use only data in PMAs approved after FDAMA's effective date.

III. STATUTORY INTERPRETATION

CDRH is issuing this guidance in response to the conflicting interpretations of section 216 regulated industry has advanced. CDRH has concluded that it will apply section 216 to free data only in PMAs approved after November 28, 1990, the date of enactment of the SMDA. The agency does not intend to use data in PMAs approved before that date, other than data that would be available to the Center without the authority granted by section 216.

Several factors have led CDRH to develop this approach to application of section 216. A critical factor to consider was the language of the provision itself. CDRH believes the interpretation it has adopted is consistent with Congressional intent as expressed in section 216, but recognizes some parts of the industry believe the language supports a different interpretation,

Any information respecting a devices which is made available pursuant to paragraph (1) or (2) of this subsection (A) (detailed summaries of safety and effectiveness made publicly available) may not be used to establish to safety or effectiveness of another device for purposes of this Act by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section.

and some believe the provision is ambiguous. CDRH discussed at length some of the legal issues raised by its interpretation of section 216 in its response to the citizen's petition on the subject, on file with FDA's Dockets Management Branch (see Docket Number 99P2725).

Another important consideration was fairness. Sponsors of applications approved before SMDA's enactment expected, at the time their applications were approved, that CDRH would not use the data they submitted to evaluate a competitor's product. This expectation was created by express language in the MDA of 1976. The four-of-a-kind rule unsettled these expectations by freeing data contained in PMAs approved before SMDA and created a new set of rules concerning data in PMAs approved after the new law. Beginning November 28, 1990, manufacturers of all as-yet unapproved medical devices had advance notice that the agency could use data contained in their approved PMA applications following approval of the third additional PMA for a device of the same kind, in accordance with the rules of the four-of-a-kind provision. Manufacturers may have anticipated that the SMDA rule would result in an extended or permanent period of protection for data contained in the applications of devices unlikely to be the subject of four or more applications. The SMDA, however, created no settled expectation of data protection on which manufacturers of such devices could reasonably rely, as medical advances, new technologies, and a variety of other market forces will affect the number of PMAs the agency receives for a device.

A third consideration was the interest of CDRH and sponsors of new submissions in access to data from earlier PMAs, an interest that seems particularly important to understanding the successive use-of-data provisions in the FDCA. Given the restrictive, contingent, and complex data use provision section 216 replaced, the purpose of the new, relatively permissive rule appears to be to facilitate informed decision-making in several areas of device regulation by allowing greater access to PMA data. Enhanced reliance on data previously reviewed by FDA is also consistent with other provisions of FDAMA that encourage the "least burdensome" pathways to product development and approval. This consideration, then, not only reflects a reasonable policy goal of the Center, but also accords with the trend in the FDCA device provisions of increasingly relaxed data-use.

A final important consideration was the need for rules that can be understood by industry and applied by the agency. This administrative consideration combined with legal, fairness, and access concerns, was included in the agency's approach to applying section 216. This approach is to use section 216 to free data in PMAs approved after November 28, 1990, in reviewing premarket submissions, classification and reclassification, and establishing special controls and performance standards for devices, but to forego use of data in PMAs approved before that date.

PROCEDURES FOR USE OF DATA FROM APPROVED PMAS

A. For what purpose can CDRH use data made available by the revised section 520(h)(4)?

Information available for use under the revised section 520(h)(4) may be used to:

1. approve another applicant's device;

2. determine whether another applicant's product development protocol has been completed;
3. establish a performance standard or special control; or
4. classify or reclassify another device under section 513 (Classification of Devices Intended for Human Use) and section 520(l)(2) (Transitional Provisions for Devices Considered as New Drugs or Antibiotic Drugs).

Information that can be used in support of the above includes data from clinical and preclinical tests or studies that were used to demonstrate the safety and effectiveness of a device. In addition, FDA may now use the publicly available detailed Summary of Safety and Effectiveness Data (SSED) required by section 520(h)(1)(A) as the evidentiary basis for any of the above four actions. FDA *may not* use information about the method of manufacture, product composition or other trade secrets found in the PMA, unless the information is otherwise publicly available to the agency. A trade secret as defined in 21 CFR 20.61 may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.

Applicants who want CDRH to use data made available by FDAMA section 216 need to provide a detailed justification of how the information in the earlier SSED applies to the applicant's device and submission. In addition, the applicant needs to describe how the devices are similar enough to allow for the data from the earlier device to apply to the new device.

CDRH believes that, while the six-year provision may be used for 1 and 2 above, it will be most useful for CDRH and the industry when it is used as a tool to initiate reclassification, to develop a standard or special control, to develop new guidance documents for a specific device or to modify current guidance documents to reduce the burden of a specific device's data requirements. Reduction in the level of preclinical and/or clinical data requirements in a marketing application will depend on the similarities in device characteristics and performance and the intended use.

B. How will six-year data be identified?

Applicants who want to use the six year provision to support their marketing application (PMA or PDP) may identify pertinent sections of the SSED from an already approved device that they want CDRH to consider when reviewing their application for a new device. In addition, an interested person may identify information described in an SSED or other publicly available document (see "Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review" available at <http://www.fda.gov/cdrh/modact/evidence.html>) that they believe to be useful as a tool to implement reclassification procedures, develop a standard or special control, to develop new

guidance documents for a specific device or modify current guidance documents to reduce data requirements. An interested person should discuss the use of this provision with the appropriate ODE review division.

FDA may also, upon its own initiative, identify information available under the six-year rule for any of the uses authorized by the statute. FDA did identify such information in its proposal to downclassify lithotriptors. However, an applicant or petitioner should not rely upon FDA to identify useful data in any particular situation.

C. Does the six-year data provision mean FDA can disclose data to my competitors?

No. The six-year provision enables FDA to use certain data in taking the regulatory actions specified in 520(h)(4) of the act. It does not authorize FDA to disclose data that would otherwise be protected from disclosure. Sponsors of competitor products may be able to benefit by relying on your data 6 years after FDA approves your PMA; however, they will not gain any new rights to see your data under this provision.

D. How will I know when data in my approved PMA are used in support of an application, reclassification, or special control?

FDA plans to identify in the SSED for the new device the PMA SSED number that contained the data that were used in support of a PMA or PDP application, reclassification petition response, or FR document announcing development of a special control. The agency is interested in receiving comments and suggestions on this proposed method of notification.

E. How will use of these data affect the confidentiality of the data?

Because section 520(h)(4) does not authorize FDA to disclose data, the provision does not compromise the data's confidentiality. Use of data under this provision does not constitute disclosure of the data to a member of the public, and does not make confidential data available to the public.

FDA will train its review staff to determine what can reasonably be considered relevant and least burdensome to the applicant and the agency in accepting prior testing available under the six-year rule. FDA will also instruct staff with regard to the limits of section 520(h)(4) of the act, which expressly exclude use of methods of manufacture and product composition and other trade secrets from the kinds of data available under the six-year provision. CDRH review staff will also be trained to consult with their supervisors, the Freedom of Information Staff, and the Office of Chief Counsel, when questions arise with respect to this new provision

Interested applicants may also contact the Program Operations Staff at 301-594-2186 or the appropriate division review staff for help with the scientific review requirements related to the device and the use of the six-year provision.