UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 30 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Christopher L. Bell, Esq.
Sidley & Austin
1722 Eye Street, N.W.
Washington, D.C. 20006

Re: TSCA/FFDCA Jurisdiction
PC-1970

Dear Mr. Bell:

This letter responds to your March 17, 1993 letter to this office, subsequent telephone conversations with Heidi Siegelbaum of my staff, as well as a September 9, 1993 meeting with EPA staff regarding the applicability of the Toxic Substances Control Act ("TSCA") to "devices", as defined in Section 201 of the Federal Food, Drug and Cosmetic Act ("FFDCA").

"Chemical substance," as defined by TSCA Section 3(2), excludes any device (defined by section 201 of the FFDCA) when manufactured, processed, or distributed in commerce for use as a device. 15 U.S.C. §2602(2)(B)(vi). To the extent that what would otherwise be considered a new chemical substance subject to the reporting requirements of Section 5(a)(1) of TSCA, is used exclusively as a component of a "device", as defined in the FFDCA, the manufacturer of the chemical substance would not be subject to TSCA. As you cite in your letter, the Environmental Protection Agency ("EPA" or "the Agency") has previously indicated that chemical substances which are intended for use as a component of a device are encompassed within the meaning of "device," as defined in the FFDCA, and hence subject to regulation under the FFDCA. 42 Fed. Reg. at 64586.

EPA considers that once a substance comes within the definition of a "device" as defined in section 201 of the FFDCA, TSCA does not apply to the chemical substance or mixture. Should a manufacturer develop an intent to use a chemical substance for a use other than that regulated by FFDCA, the substance may be subject to TSCA. If the chemical substance is considered a "new" substance because it is not already on the TSCA Chemical Substance Inventory and not otherwise excluded or exempt, it would be subject to PMN reporting under Section 5(a)(1).

Once the determination has been made that a chemical substance is intended to be used exclusively as a component of a "device," as that term is defined by the FFDCA, EPA considers FDA as having jurisdiction over the review of that substance. FDA's right to exercise its discretion by electing, as a matter of policy, not to evaluate or regulate a chemical substance used as a component in a device or the device itself, despite the fact that it has jurisdiction and legal authority to regulate, does not enable EPA to assume jurisdiction over the chemical under TSCA.

In your letter you state that when the chemical substance is a component or accessory of a medical device, or is used in the manufacture of a medical device (or its components or accessories), it should be exempt from future TSCA §4 or §8 obligations while the same chemical used in industrial applications would continue to be subject to §§4 and 8 of TSCA.

Chemical substances which are considered components or accessories of a medical device would fall within FFDCA jurisdiction only if, inter alia, they were intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in [human beings] and other animals. 21 CFR §201(h)(2).

You raise a number of examples for which you seek EPA consensus:

(1) Chemicals that are manufactured, imported, processed or used solely for inclusion in products or goods that are medical devices as defined by the FFDCA.

EPA interprets "inclusion" to mean any component which is intended to be used as part of the device. Components include items used in the production of the device or a chemical substance which is part of the device. Components include precursors, intermediates, and catalysts used in production. These chemical substances would not be subject to TSCA jurisdiction.

For TSCA jurisdictional issues, the only relevant issue is whether a product meets the definition of "device" under the FFDCA. Issues pertaining to the manner in which FDA regulates devices, e.g.; classification, good manufacturing practices, etc. are not relevant to the issues you have raised. Therefore, references to types of FDA regulation have been deleted in our response. I would suggest contacting Kay Cook, FDA's Assistant General Counsel for Devices at (301) 443-7272.

(2) As stated above, chemical components of devices (including finished medical devices) and associated impurities (all are considered unintentionally generated), are not subject to TSCA. The Agency is currently investigating and addressing concerns regarding the applicability of TSCA to pharmaceutical wastes and processing effluents of which unintentionally generated impurities could ostensibly be a part.

(3) Chemical components of devices that are received from third parties.

These components are not subject to TSCA if the chemical substance meets the description of a component of a device as described herein at paragraph 1. For your information, it is my understanding from FDA that manufacturers of raw materials are generally exempt from FDA registration requirements.

Assuming that the third party is a manufacturer who intends to develop a TSCA use for the chemical substance, it is incumbent on that person to evaluate potential reporting liability under TSCA. The recipient is subject to liability under TSCA §15(2) if they use the chemical for a commercial purpose where they know or have reason to know that the chemical is being manufactured, processed, or distributed in commerce in violation of section 5 or 6, a rule or order under section 5 or 6, or an order issued in action brought under section 5 or 7.

(4) Chemical byproducts which are inadvertently generated during the manufacture of devices.

Such byproducts would be subject to TSCA jurisdiction when those byproducts are intended to be distributed in commerce as a "chemical substance" as defined at TSCA Section 3(2)(A). It is also clear that the generation of such byproducts containing new chemical substances would be subject to the Section 5 PMN requirements of TSCA if they had a commercial use which fell outside the scope of the excluded uses described at 40 CFR 720.30(g) [the exclusion's scope is as follows: burn as a fuel; dispose as a waste; or extract component chemical substances from it for commercial purposes].

(5) "Rare earth" compounds or any chemical substances which are imported into the U.S., some non-separable portion of which is processed for inclusion into a product which is <u>not</u> a medical device. The part of the process which produces the chemicals for use in the medical device is excluded from TSCA unless it cannot be separated from the process which produces chemicals for the non-FFDCA purpose.

The entire production volume -- some of which is used for TSCA purposes and some of which is used in devices, is reportable under TSCA if the portion used for TSCA purposes is <u>not</u> separable.

(6) During the manufacture of a device, a chemical impurity is produced which becomes an integral part of the finished device. The manufacture or distribution of the impurity in the device is not regulated by TSCA.

As you are aware, any impurity (defined at 40 CFR 720.3(m) as a chemical substance which is unintentionally present with another chemical substance) is excluded from PMN requirements by 40 CFR 720.30(h)(1).

(7) During the manufacture of a device, a chemical byproduct is produced which is disposed of and is not present in the finished device.

The disposal of a byproduct of a device disposed of as a waste is still under Agency consideration. You should also consult with appropriate Federal, state and local authority and the Resource Conservation and Recovery Act (RCRA) to ascertain what disposal regulations may apply.

(8) Lead and other chemicals are imported into the U.S. solely to be processed into X-Ray shielding for medical devices. The lead and other chemicals are not regulated by Section 4,5, and 8 of TSCA at the time of importation, during the processing, nor after their use in medical devices.

As stated in response to question 1 above, chemical substances, provided no TSCA use is developed nor intended for lead and these other chemicals, would not be reportable under the sections of TSCA you cite above. However, the question of TSCA jurisdiction over lead or any chemical substance as an impurity or byproduct of a device intended for disposal is still under consideration.

(9) Chemicals imported, repackaged and used solely as part of a repair and maintenance kit for medical devices. If these substances are accessories to those devices, you argue that they are not regulated by Sections 4, 5 and 8 of TSCA. You further contend that if the maintenance kit is exported, it should be exempt from Section 12 of TSCA.

Whether chemicals which are used in repair and maintenance kits are "accessories" is a question which you should raise with FDA staff. It is arguable that chemical substances used in repair kits where the chemical does not become part of the article may be "chemical substances" subject not only to Sections 4 and 8, but perhaps Section 5 if they are "new," and Section 12 if they are exported.

Certain related issues are still under consideration. OPPT staff met with FDA representatives on January 27, 1994 to further discuss and clarify these issues. Should you have a specific case which requires resolution, we encourage you to set forth the specific facts of your case to enable EPA staff to help resolve any outstanding jurisdictional issues which may be raised. Finally, many of the questions you raise require FDA to render affirmative opinions regarding jurisdiction over the chemical substances somehow associated with the manufacture and use of medical devices. We encourage you to solicit such opinions from the appropriate Office of General Counsel at FDA.

Should you have further questions or comments regarding the issues raised in this letter, please contact Heidi Siegelbaum of my staff at (202) 260-8262.

Sincerely,

Charles M. Auer, Director
Chemical Control Division

cc: Heidi Siegelbaum

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202-736-8118

March 17, 1993

Carol L. Hetfield
Miriam G. Wiggins-Lewis
Premanufacture Notification Coordinators
U.S. Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
E609C/TS-794
401 M Street, S.W.
Washington, D.C. 20460

re: TSCA/FFDCA Jurisdiction.

Dear Ms. Hetfield and Wiggins-Lewis:

I am writing to seek clarification on an important matter for the medical device industry: the relationship between the Toxic Substances Control Act and the Federal Food, Drug and Cosmetic Act as it applies to the regulation of chemicals used in the development, manufacture, distribution and servicing of medical devices. In a February 3, 1993 telephone discussion, Roy S. Seidenstein of your office informed me that components used in the manufacture or processing of medical devices, including chemical intermediates, are not regulated by TSCA. This general proposition raises several issues on which I have not been able to find specific EPA guidance. It is important to the medical device industry that this uncertainty be eliminated so that it can predictably determine to what extent its activities are regulated by TSCA. This letter suggests a series of standards and seeks EPA's confirmation of these interpretations.

First, it may be helpful to summarize existing law and EPA's interpretations of the law. TSCA excludes from the definition of chemical substance any "device (as such terms are defined in section 201 of the Federal Food, Drug and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a . . . device." 15 U.S.C.

§ 2602(2)(B)(vi) (emphasis added); see 40 C.F.R. § 720.3(a)(1) and (e)(6). The FFDCA defines a device as any

> instrument, apparatus, implement, . . . or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease . . . or the cure . . . or prevention of disease, or (3) intended to affect the structure of any function of the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes and which does not achieve its primary intended purposes through chemical action within or on the body.

21 U.S.C. § 321(h) (emphasis added). The scope of products that have been deemed medical devices is broad, including items such as phonograph records used as sleeping aids,[1] toothbrushes,[2] surgical instrument sterilizers[3] and sunglasses.[4] A component is defined as "any material, substance, piece, part, or assembly used during device manufacture which is intended to be included in the finished device." 21 C.F.R. § 820.3(c). Examples of components or accessories that are medical devices include pacemaker repair or replacement material, including adhesives and sealants,[5] wheelchair accessories such as cane holders and leg rest straps,[6] attachments for surgical instrument motors such as burs, chisels, drill bits

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[1] U.S. v. 23 Articles, 192 F.2d 308 (2d Cir. 1951)

[2] U.S. v. 2,000 Plastic Tubular Cases, 231 F.Supp. 236 (E.D. Pa. 1964), aff'd. 352 F.2d 344, cert. denied, 383 U.S. 913 (1965).

[3] U.S. v. 22 Rectangular or Cylindrical Finished Devices, 714 F. Supp. 1159 (D. Utah 1989).

[4] Truxillo v. Ray-Ban, Civ. No. 91-1558 (E.D. La. August 12, 1992).

[5] 21 C.F.R. § 870.3710

[6] 21 C.F.R. § 890.3910(a). Wheelchair accessories are devices intended for medical use which are sold separately from the wheelchair. Wheelchair components are defined separately as devices that are intended for medical purposes and generally sold as an integral part of a wheelchair, but may also be sold separately as a replacement part. 21 C.F.R. § 890.3920(a).

and saw blades,[7] and leaded x-ray glass used in doors or windows of radiation treatment rooms.[8]

As a general matter, EPA has stated that chemical intermediates used in the production of drugs are not regulated by TSCA. 42 Fed. Reg. 64572, 64586 (December 23, 1977); Question and Answer Summary, EPA Seminar on Industry Obligations Under TSCA (May 5, 1987), p. 11; Questions and Answers Concerning the TSCA Section 8(c) Rule, p. 38 (EPA November 10, 1983); Toxic Substances Control Act: A Guide for Chemical Importers/Exporters, Vol. 1, pp. 51-52. However, there is relatively little direct guidance on the application of this principle to medical devices.

Consistent with its position on drugs, EPA has written that the "definitions of the FFDCA provide that chemical substances which are intended for use as a component of a . . . device are encompassed within the meanings of such terms . . ." and that therefore "they are subject to regulation under the FFDCA." 42 Fed. Reg. at 64586. Continuing, the Agency said that "as soon as FDA regulates a product, its manufacture, processing or distribution in commerce solely for a FDA regulated use will be excluded from the jurisdiction of TSCA." Id. In the same vein, EPA stated that "[t]he manufacture of polymers for use in medical devices would be exempt from 8(c) provided the entire process was regulated by FDA. Otherwise, only those portions of the manufacturing process that are regulated by FDA are exempt from TSCA." Questions and Answers Concerning the TSCA Section 8(c) Rule, p. 39 (EPA November 10, 1983).

However, this general guidance still leaves open two basic questions: (1) when is a device "regulated by FDA" such that it is no longer in the purview of TSCA, and (2) when a device is regulated by FDA, what is the scope of the exclusion from TSCA? In addition, it appears that the Agency's interpretation of TSCA's jurisdiction is broader than that set forth in the statute. The statute provides that the term "chemical substance" does not include any device as such term is defined in section 201 of the FFDCA. Therefore, the operative question should not be whether and how FDA regulates a medical device or its components, but rather whether the chemical substance falls under the statutory or regulatory definition of device. Once a chemical substance is defined as a device, which includes components and accessories of a device, and that chemical substance is manufactured,

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[7] 21 C.F.R. § 878.4820(a).

[8] Letter from Richard M. Cooper, Chief Counsel, to Theodore J. Garrish, General Counsel U.S. Consumer Product Safety Commission (January 4, 1978). Based upon this opinion, the CPSC concluded that the leaded x-ray glass was excluded from the definition of consumer product, a definition which, analogous to TSCA's definition of chemical substances, excludes medical devices. CPSC Advisory Opinion # 257 (January 24, 1978).

processed, or distributed in commerce for use as a device, including a component or accessory of a device, TSCA jurisdiction over that chemical substance ceases.

EPA does give one specific example of when a medical device might be exempted from TSCA: the submission of an application to FDA for an exemption for the investigational use of a device pursuant to Section 502(g) of the FFDCA. 42 Fed. Reg. at 64586. However, this example is limited to investigative devices that have not entered commercial distribution. It does not provide any guidance concerning the broad range of devices, including components and accessories, that are commercially available. In addition, EPA has not provided any guidance on the equally important issue of the scope of the FDA exclusion from TSCA should it be determined that the exclusion does apply to a medical device (including its components and accessories). This issue may arise in the context of a chemical that is used in both industrial applications and medical devices. When the chemical is a component or accessory of a medical device, or it is used in the manufacture of a medical device (or its components or accessories), it should be exempt from future TSCA Section 4 or 8 obligations, while the same chemical used in industrial applications would continue to be subject to Sections 4 or 8 of TSCA.

EPA must clarify these issues and provide the medical device industry with specific guidance as to where FDA's jurisdiction begins and EPA's TSCA jurisdiction ends. In the original TSCA Inventory rulemaking, EPA recognized that "the interrelationship of TSCA, FIFRA, and FFDCA is complex and that jurisdictional issues need further exploration in light of the various types of regulatory situations that may arise and the Congressional intent of avoiding both dual jurisdiction and regulatory gaps." 42 Fed. Reg. at 64585. This remains true today with respect to what FDA regulation exempts medical devices from regulation under TSCA.

In an attempt to establish more explicit guidance on this issue, it is my understanding, based upon the statutory language and policy and EPA's regulations and interpretative statements, that the following are correct interpretations of the relationship between TSCA and the FFDCA.

- Chemicals that are manufactured, imported, processed or used solely for inclusion in products or goods that are medical devices as defined by the FFDCA and therefore subject to the FDA's "Medical Device Classification Procedures" (21 C.F.R. Part 860) are not subject to TSCA jurisdiction.

- Chemicals that are manufactured, imported, processed or used solely for inclusion in medical devices that are Class I devices, for which a premarket notification has been submitted pursuant to 21 C.F.R. Part 807 (Class II devices), for which a premarket approval application has been submitted pursuant to 21 C.F.R. Part 814 (Class III

devices), or for which an Investigational Device Exemption application has been submitted pursuant to 21 C.F.R. Part 812, are not subject to TSCA jurisdiction.

- Chemical components of finished medical devices, including unintentionally generated impurities, are not subject to TSCA jurisdiction when the manufacture of the finished medical devices is subject to FDA's "Good Manufacturing Practices" (21 C.F.R. Part 820).

    - Chemical components of finished medical devices that are received from third parties and are managed in accordance with the "Control of Components" procedures of Subpart E of 21 C.F.R. Part 820 are not subject to TSCA jurisdiction.

    - Chemical byproducts which are inadvertently generated during the manufacture of finished medical devices which are fabricated in accordance with Good Manufacturing Practices are not subject to TSCA jurisdiction when those byproducts are not intended to be, and are not, distributed in commerce.

The following examples illustrate the application of these interpretations.

- "Rare earth" compounds which are imported into the United States and processed solely for inclusion into medical devices which are manufactured in accordance with FDA's Good Manufacturing Practices (21 C.F.R. Part 820) are not regulated by TSCA, including Sections 4, 5 and 8 of TSCA.

    - If some of those chemicals are also processed for use in a product which does not meet the FFDCA definition of a device, only the portion used solely in the medical device would continue to be exempt from all sections of TSCA. That part of the process which produces the chemicals for use in the medical device is also exempt from TSCA unless it cannot be separated from the process which produces chemicals for the non-FFDCA purpose.

- During the manufacture of a finished medical device, a chemical impurity is produced which becomes an integral part of the finished device. The manufacture or distribution of the impurity in the device is not regulated by TSCA.

- During the manufacture of a finished medical device covered by FDA's Medical Classification Procedures and the Good Manufacturing Practices, a chemical byproduct is produced which is disposed of and is not present in the finished device. The manufacture and disposal of the byproduct is not subject to TSCA jurisdiction.

- Lead and other chemicals are imported into the United States solely to be processed into X-Ray shielding for medical devices. The lead and other chemicals are not regulated by Sections 4, 5 and 8 of TSCA at the time of importation, during the processing, nor after their use in medical devices.

- Chemicals imported, repackaged and used solely as part of a repair and maintenance kit for medical devices are "accessories" to those devices and therefore are not regulated by Sections 4, 5 and 8 of TSCA. If the kit is exported, it should be exempt from Section 12 of TSCA.

I believe that these interpretive standards and examples are consistent with the law and EPA's past statements on the issue.

Obtaining specific and practical guidance on this matter is of considerable importance to the medical device industry. I will be calling you soon to answer any questions you might have and to schedule a meeting to discuss these issues. If you have any questions before then, please do not hesitate to call me at (202) 736-8118.

Sincerely,

Christopher L. Bell

cc: Roy S. Seidenstein (EPA)
F. Alan Andersen, Ph.D. (FDA)