Subpart E—Termination

22. Revise § 158.81 to read as follows:

§ 158.81 General.

This subpart contains the procedures for terminating PFCs or loss of Federal airport grant funds for violations of this part or 49 U.S.C. 40117. This subpart does not address the circumstances under which authority to collect PFCs may be terminated for violations of 49 U.S.C. 47523 through 47528.

§ 158.97 [Removed]

23. Remove § 158.97.

24. Amend appendix A by revising paragraphs 10 and 12 of section B to read as follows:

Appendix A to Part 158—Assurances

* * * * *

B. * * *

* * * * *

10. Recordkeeping and Audit. It will maintain an accounting record for audit purposes for 3 years after physical and financial completion of the project. All records must satisfy the requirements of 14 CFR part 158 and contain documentary evidence for all items of project costs.

* * * * *

12. Compliance with 49 U.S.C. 47523 through 47528. It understands 49 U.S.C. 47524 and 47526 require the authority to impose a PFC be terminated if the Administrator determines the public agency has failed to comply with those sections of the United States Code or with the implementing regulations published under the Code.

Issued in Washington, DC, on January 26, 2006.

Dennis E. Roberts,

Director, Office of Airport Planning and Programming.

[FR Doc. 06–896 Filed 1–31–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 203 and 205

[Docket No. 2005N–0428]

Distribution of Blood Derivatives by Registered Blood Establishments that Qualify as Health Care Entities; Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements and Administrative Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to amend the regulations to allow certain registered blood establishments that qualify as health care entities to distribute drug products that are derivatives of blood (blood derivatives). This proposed rule, which is specific to registered blood establishments and the distribution of blood derivatives, if finalized, would amend certain limited provisions of the regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA) and the FDA Modernization Act of 1997. As currently written, these regulations, among other things, restrict the sale, purchase, or trade of, or the offer to sell, purchase, or trade, prescription drugs purchased by hospitals and other health care entities.

DATES: Submit written or electronic comments on the proposed rule by May 2, 2006.

ADDRESSES: You may submit comments, identified by Docket No. 2005N–0428, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kathleen Swisher, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

The PDMA (Public Law 100–293) was enacted on April 22, 1988, and was modified by the PDA (Public Law 102–353, 106 Stat. 941) on August 26, 1992. The PDMA, as modified, amended the Federal Food, Drug, and Cosmetic Act (the act) to establish restrictions and requirements relating to various aspects of human prescription drug marketing and distribution. Among other things, the PDMA prohibited, with certain exceptions, the sale, purchase, or trade (or offer to sell, purchase, or trade) of prescription drugs that were purchased by hospitals or other health care entities. Section 503(c)(3)(A)(ii)(I) of the act (21 U.S.C. 353(c)(3)(A)(ii)(I)). Section 503(c)(3) also states that ''[f]or purposes of this paragraph, the term 'entity' does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law * * *.''

In the **Federal Register** of March 14, 1994 (59 FR 11842), we issued a proposed rule to implement those PDMA sections that were not implemented by the final rule of September 14, 1990, that set forth Federal guidelines for State licensing of wholesale drug distributors (55 FR 38012). The proposed rule contained provisions on prescription drug reimportation; wholesale distribution of prescription drugs by unauthorized distributors; the resale of prescription drugs by hospitals, health care entities, and charitable institutions; and distribution of prescription drug samples. After consideration of comments, we issued a final rule in the **Federal Register** of December 3, 1999

(64 FR 67720) (''the final rule''), with an effective date of December 4, 2000.

After publication of the final rule, we received many letters on, and held several meetings to discuss the implications of, the final regulations for registered blood establishments that distribute blood-derived products and provide health care as a service to hospitals and patients. According to comments received before the final rule took effect, implementing the final rule as published would interfere with longstanding relationships between blood centers and other health care providers such as hospitals, hemophilia treatment centers, and other providers.

The blood establishment industry asserted that the regulations, particularly the definition of ''health care entity'' in § 203.3(q) (21 CFR 203.3(q)), would, to the detriment of the public health, severely inhibit its ability to provide medical care and services and might disrupt the distribution of blood derivatives, to what may be otherwise unserved or inadequately served segments of the public. Specifically, § 203.20 (21 CFR 203.20) of the final rule as written states, in relevant part, that no person may sell, purchase, or trade, or offer to sell, purchase, or trade any prescription drug that was purchased by a health care entity (§ 203.20(a)).

''*Health care entity*'' is defined in § 203.3(q) as any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or wholesale distributor. That definition specifically states that, ''A person cannot simultaneously be a 'health care entity' and a retail pharmacy or wholesale distributor.'' ''*Wholesale distributor*'' is defined in § 203.3(dd) (21 CFR 203.3(dd)) as any person engaged in wholesale distribution of prescription drugs, and ''*wholesale distribution*'' is defined in § 203.3(cc) (21 CFR 203.3(cc)) as ''distribution of prescription drugs to persons other than a consumer or patient * * *.'' The final rule made clear that those definitions should be interpreted to mean that an establishment that meets the definition of a health care entity would not be allowed to engage in wholesale distribution. The **Federal Register** of December 3, 1999, stated ''The agency declines to revise the definition of health care entity or otherwise revise the proposed rule to permit health care entities to engage in the wholesale distribution of blood derivatives or other prescription drug products.'' (64 FR 67720 at 67726).

Thus, under the final rule as written, blood establishments functioning as health care entities would not be allowed to engage in wholesale distribution of prescription drugs except for blood and blood components intended for transfusion, which are exempted from the regulations under § 203.1 (21 CFR 203.1). As discussed in the preamble to the final rule (64 FR 67720 at 67725 to 67727), blood derivatives are not blood components. Therefore, should the final rule go into effect as written, registered blood establishments that qualify as health care entities could not distribute blood derivatives.

Blood derivatives that are prescription drugs include the following: Albumin, antihemophilic factor, Factor IX Complex, alpha-1 anti-tripsin, and immune globulin. Therefore, under the rule as written, a blood center could not resell blood derivatives to entities other than consumers or patients and simultaneously provide health care, such as medical services associated with those products.

On May 3, 2000, we delayed until October 1, 2001, the effective date of several provisions of the final rule and reopened the administrative record, giving interested persons until July 3, 2000, to submit written comments (65 FR 25639). This delay extended to the definition of ''*health care entity*'' in § 203.3(q), as applied to the wholesale distribution of blood derivatives by health care entities. The purpose of delaying the effective date for these provisions was to give us time to obtain more information about the possible consequences of implementing these provisions and to further evaluate the issues involved (65 FR 25639 at 25641).

On September 19, 2000, we announced a public hearing to discuss certain requirements of the final rule (65 FR 56480), including the provisions relating to the distribution of blood derivatives by entities that meet the definition of ''health care entity.'' We held the public hearing to develop an adequate factual basis to use to determine whether it is in the public health interest to modify or change the requirements in the final rule (65 FR 56480 at 56483).

We developed a list of questions to promote a more useful discussion at the public hearing. These questions related to: The distribution systems available for blood derived products; the effect of the final rule on these distribution systems, including adverse public health consequences or economic costs; whether excluding blood derived products from the final rule's restrictions would increase the risk of distribution of counterfeit, expired, adulterated, misbranded, or otherwise unsuitable products; and the pricing of blood-derived products sold to health care entities (65 FR 56480 at 56483) with regard to blood derivatives, as well as other unrelated issues associated with wholesale distribution of drugs. This proposed rule addresses only blood derivatives and does not address the other stayed requirements in the final rule relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record (69 FR 8105, February 23, 2004).

The public hearing was held on October 27, 2000, and comments were accepted until November 20, 2000. In the **Federal Register** of March 1, 2001, we announced our decision to further delay until April 1, 2002, the applicability of § 203.3(q) to the wholesale distribution of blood derivatives by health care entities (66 FR 12850). Further delays of effective dates followed until December 1, 2006, to give us additional time to consider whether regulatory changes are appropriate and, if so, to initiate such changes (67 FR 6645, February 13, 2002; 68 FR 4912, January 31, 2003; 69 FR 8105, February 23, 2004).

We now propose to amend the regulations. The proposed amendments are narrow and would allow certain registered blood establishments that qualify as health care entities to distribute blood derivatives.

II. The Blood Establishments' Concerns

In response to the final rule, we received numerous comments arguing that blood establishments should be allowed to continue performing both functions of providing health care services and distributing blood derivatives. Some comments asserted that although the distribution of derivatives and the provision of health care services are small parts of a blood establishment's activities, they are vital to serving public health needs.

At the October 2000 public hearing, we heard from four interested parties on this subject. Comments asserted that we had reached the wrong conclusion with respect to restrictions on blood establishments' activities. In addition to restating earlier objections made in response to the proposed rule, the comments presented new objections and new information, including more detailed descriptions of the health care services they provide and the derivatives they distribute. They also offered several potential regulatory solutions.

We received no comments taking the position that the regulations should

remain unchanged. We received from a national trade organization that represents blood establishments additional comments about the scope of products they distribute for treating blood-related disorders, which include drugs that are not blood derivatives. The comment stated the exemption should extend to any distribution of blood-related products by blood centers, not just to blood derivatives because blood centers also distribute blood-related products not always from human sources. In this proposed rule, we are seeking additional information on the distribution of other prescription drug products by registered blood establishments.

We have considered all comments and have changed our position from that expressed in the preamble discussion in the December 3, 1999, final rule (64 FR 67720). We now propose to allow certain registered blood establishments that qualify as health care entities to distribute blood derivatives. We are distinguishing blood derivatives from other prescription drugs when sold, purchased, or traded (or offered to sell, purchase, or trade) by a registered blood establishment that qualifies as a health care entity, provided all health care services offered by the establishment are related to its activities as a registered blood establishment.

III. The Proposed Amendments

Our current proposal modifies part 203 (21 CFR part 203) to allow a registered blood establishment [1] that provides health care services and that also distributes blood derivatives to continue in both capacities, as long as the blood establishment does not provide health care services unrelated to its activities as a registered blood establishment.

We have changed our position from that discussed in the preamble to the final rule (64 FR 67720 at 67726) because of new information and a better understanding of the industry and how the final rule, if enforced, might affect the public health. For example, according to testimony at the public hearing held on October 27, 2000, ''more than 15 percent of all U.S. blood derivative products are distributed by community and Red Cross blood centers, with Red Cross alone accounting for 10 percent.'' [2] Those blood centers qualify as health care entities because, in addition to collecting blood and plasma and distributing blood derivatives, they also provide certain health care services to the hospitals and health care entities they serve, including therapeutic phlebotomy, plasma exchange, stem cell and cord blood collection and processing, and medical expertise on the appropriate use of the blood derivatives they distribute.[3] According to the testimony, the majority of local hospitals do not have that kind of medical expertise, and as a practical matter could not obtain and maintain such expertise.[4]

Prohibiting community and Red Cross blood centers that qualify as health care entities from distributing blood derivatives would have a particularly high impact on certain segments of patients. For example, the Red Cross testified that ''85 percent of their anti-hemophilic factor is supplied directly to health care entities. They stated that implementation of the final rule would deny hemophilia patients access to this product because many treatment centers are smaller entities that are not supported by large distributors.'' [5] Additionally, the Red Cross stated that ''15 percent of their IVIG (intravenous immunoglobulin) products and 10 percent of their albumin product are provided directly to healthcare providers and account for 26,000 to 69,000 infusions annually.'' [6]

We now propose to amend § 203.22 (21 CFR 203.22), which contains exclusions from the sales restrictions in § 203.20 (21 CFR 203.20). Proposed new paragraph (h) provides a limited exception for registered blood establishments that qualify as a health care entity. Under the proposed exclusion, the sales restrictions in § 203.22 would not apply to the sale, purchase, or trade of (or the offer to sell, purchase, or trade) any blood derivatives by a registered blood establishment that qualifies as a health care entity as long as all of the health care services that it provides are related to its activities as a registered blood establishment. The following are examples of such health care services: therapeutic hemapheresis, therapeutic phlebotomies, plasma exchange, and transfusion services. For clarification, a registered blood establishment's ordinary donor screening activities for donor suitability (e.g., measuring a donor's temperature, blood pressure, and hematocrit or hemoglobin) are not considered health care services for the purposes of § 203.3(q).

A registered blood establishment that provides any health care services unrelated to its activities as a registered blood establishment would not be eligible for the exclusion. For example, if a registered blood establishment provides health care services such as administering antibiotics to treat a respiratory infection unrelated to transfusion medicine, we do not consider this to be a health care service related to the operation of a blood establishment. Therefore, the blood establishment would not be permitted to distribute blood derivatives. Without that limit on the exclusion, the rule would encourage hospitals and other health care entities to register as blood establishments strictly to take advantage of this exception. Allowing such entities that are not primarily blood establishments to distribute blood derivatives could raise the same concerns that the PDMA was intended to address. The prohibition against sales by health care entities was prompted in part because of the temptation for such entities to sell for-profit drugs acquired at below-wholesale prices.

The proposed exclusion in § 203.22 applies only to the distribution of blood derivatives by a registered blood establishment and not by other entities. The regulations implementing the PDMA, as modified, would continue to apply to these other entities.

Although the public hearing and additional comments received on the final rule provided us with an adequate factual basis to determine whether the requirements in the final rule should be modified in the interest of public health, new information provided with respect to the function of registered blood establishments indicates that additional input is needed. We are seeking information about the functions of registered blood establishments to assist us in making a decision whether further modification of the final rule is necessary in the interests of public health.

Proposed § 203.22(h) includes an ''exclusion'' that would allow certain registered blood establishments that qualify as health care entities to distribute blood derivatives. In consideration of the issues that the industry raised, we seek comments on whether this exclusion should be

[1] Establishment is defined as ''a place of business under one management at one general physical location. The term includes, among others, human blood and plasma donor centers, blood banks, transfusion services, other blood product manufacturers and independent laboratories that engage in quality control and testing for registered blood product establishments.'' (§ 607.3 (21 CFR 607.3)) All owners or operators of establishments that engage in the manufacturing of blood products are required to register, under section 510 of the Federal Food, Drug, and Cosmetic Act (§ 607.7 (21 CFR 607.7)).

[2] U.S. Food and Drug Administration, ''The Prescription Drug Marketing Act: Report to Congress,'' June 2001, p.17 and p.18.

[3] Id., at 18.

[4] Id.

[5] Id.

[6] Id.

expanded to allow registered blood establishments that also provide health care services to distribute drugs other than blood derivatives that might be used to treat blood disorders. We are seeking information that includes, but is not limited to, the number of entities affected; how often drugs used to treat blood disorders are distributed by registered blood establishments and whether the nature of this practice is critical; and, any negative impact on public health if the exclusion allows only for the distribution of blood derivatives. Actual numbers, statistics, and examples would help us determine the best course of action. In addition, we seek comments on whether hemophilia treatment centers, which are health care entities but are not registered blood establishments, should be included within the scope of this exception.

IV. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA) is not required.

VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule proposes a narrow revision that is intended to maintain the status quo, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 203

Drugs, Labeling, Manufacturing, Prescription drugs, Reporting and recordkeepng requirements, Warehouses.

21 CFR Part 205

Intergovernmental relations, Prescription drugs, Reporting and recordkeeping requirements, Security measures, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that parts 203 and 205 be amended as follows:

PART 203—PRESCRIPTION DRUG MARKETING

1. The Authority citation for 21 CFR part 203 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 351, 352, 353, 360, 371, 374, 381.

2. Section 203.3 is amended by revising paragraph (q) to read as follows:

§ 203.3 Definitions.

* * * * *

(q) *Health care entity* means any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. Except as provided in § 203.22(h), a person cannot simultaneously be a ''health care entity'' and a retail pharmacy or wholesale distributor.

* * * * *

3. Section 203.22 is amended by adding paragraph (h) to read as follows:

§ 203.22 Exclusions.

* * * * *

(h) The sale, purchase, or trade of, or the offer to sell, purchase, or trade any blood derivative by a registered blood establishment that qualifies as a health care entity, as long as all of the health care services that it provides are related to its activities as a registered blood establishment.

PART 205—GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS

4. The Authority citation for 21 CFR part 205 continues to read as follows:

Authority: 21. U.S.C. 351, 352, 353, 371, 374.

5. Section 205.3 is amended by revising paragraph (h) to read as follows:

§ 205.3 Definitions

* * * * *

(h) Health care entity means any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. Except as provided in § 203.22(h), a person cannot simultaneously be a ''health care entity'' and a retail pharmacy or wholesale distributor.

Dated: November 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1225 Filed 1–31–06; 8:45 am]

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