FDC date	State	City	Airport	FDC No.	Subject
07/10/08	MI	MANISTEE	MANISTEE CO.–BLACKER	8/6401	VOR RWY 27, ORIG
09/04/08	GQ	AGANA	GUAM INTL	8/6576	ILS OR LOC/DME RWY 6L, AMDT 3B
09/05/08	CO	DENVER	ROCKY MOUNTAIN METROPOLITAN	8/6770	GPS RWY 29L, ORIG–A
09/05/08	CO	DENVER	ROCKY MOUNTAIN METROPOLITAN	8/6771	GPS RWY 29R, ORIG–A
09/05/08	MT	BUTTE	BERT MOONEY	8/6864	ILS Y RWY 15, AMDT 6
09/05/08	MT	ANACONDA	BOWMAN FIELD	8/6866	VOR/DME OR GPS A, AMDT 1
09/05/08	OR	EUGENE	MAHLON SWEET FIELD	8/6867	ILS OR LOC/DME RWY 16L, ORIG
09/05/08	AK	PERRYVILLE	PERRYVILLE	8/6868	RNAV (GPS) RWY 2, ORIG
09/08/08	KY	DANVILLE	STUART POWELL FIELD	8/7015	LOC/DME RWY 30, AMDT 1A
09/08/08	AR	FORT SMITH	FORT SMITH RGNL	8/7062	RNAV (GPS) RWY 7, ORIG–B
09/08/08	AR	FORT SMITH	FORT SMITH RGNL	8/7064	VOR/DME OR TACAN RWY 7, AMDT 11B
09/08/08	AR	FORT SMITH	FORT SMITH RGNL	8/7065	RNAV (GPS) RWY 25, ORIG–B
09/08/08	AR	FORT SMITH	FORT SMITH RGNL	8/7067	ILS OR LOC RWY 25, AMDT 21D
09/08/08	AR	FORT SMITH	FORT SMITH RGNL	8/7068	ILS OR LOC RWY 7, ORIG–B
09/08/08	AR	FORT SMITH	FORT SMITH RGNL	8/7069	VOR OR TACAN RWY 25, AMDT 20G
09/10/08	OK	TULSA	TULSA INTL	8/7352	ILS OR LOC RWY 18R, AMDT 7
09/10/08	CA	VAN NUYS	VAN NUYS	8/7460	ILS RWY 16R, AMDT 5A
09/11/08	VA	DUBLIN	NEW RIVER VALLEY	8/7673	ILS OR LOC RWY 6, AMDT 4A
09/12/08	LA	LAFAYETTE	LAFAYETTE REGIONAL	8/7965	TAKEOFF MINIMUMS AND (OBSTACLE) DEPARTURE PROCEDURES (ODP), AMDT 1

[FR Doc. E8–23916 Filed 10–8–08; 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. FDA–2005–N–0345] (formerly Docket No. 2005N–0428)

Distribution of Certain Drug Products by Registered Blood Establishments and Comprehensive Hemophilia Diagnostic Treatment Centers 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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to allow certain registered blood establishments and comprehensive hemophilia diagnostic treatment centers that are also health care entities to distribute certain drug products. The final rule amends limited provisions of the regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA). 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: This rule is effective November 10, 2008.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0372.

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) 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 any prescription drug that was purchased by a hospital or other health care entity. 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 certain provisions of the PDMA. 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 December 1999 final rule), with an effective date of December 4, 2000.

After publication of the December 1999 final rule, we received many comments on, and held several meetings to discuss the implications of, the final regulations for registered blood establishments that distribute blood-derived products and provide limited health care services to hospitals and patients. According to comments, implementing the December 1999 final rule as published would interfere with longstanding relationships between blood centers and other health care providers such as hospitals and hemophilia treatment centers.

Section 203.20(a) (21 CFR 203.20(a)) of the December 1999 final rule stated, 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. ''Health care entity,'' in turn, was defined in § 203.3(q) (21 CFR 203.3(q))

as any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but did not include any retail pharmacy or wholesale distributor. That definition specifically stated that ''[a] person cannot simultaneously be a 'health care entity' and a retail pharmacy or wholesale distributor.''

Thus, under the December 1999 final rule as written, blood establishments and hemophilia treatment centers functioning as health care entities would be prohibited from engaging 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) (see also 21 CFR 203.22(g)). As discussed in the preamble to the December 1999 final rule (64 FR 67720 at 67725 to 67727), blood derivatives are not blood components and were therefore subject to this prohibition on wholesale distribution. Therefore, under the December 1999 final rule, a blood establishment or a hemophilia treatment center could not generally resell blood derivatives to entities other than consumers or patients and simultaneously provide health care, such as medical services associated with those products. Examples of blood derivatives that are prescription drugs include, but are not limited to, albumin, antihemophilic factor, Coagulation Factor IX, alpha-1 proteinase inhibitor, and immune globulin.

On May 3, 2000, we delayed until October 1, 2001, the effective date of several provisions of the December 1999 final rule and reopened the administrative record (65 FR 25639). In the **Federal Register** of March 1, 2001 (66 FR 12850), we announced our decision to further delay until April 1, 2002, the applicability of § 203.3(q) (definition of ''health care entity'') to the wholesale distribution of blood derivatives by health care entities. Further delays of effective dates followed until December 1, 2008, to give us additional time to consider whether regulatory changes were 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; 71 FR 66108, November 13, 2006).

In the **Federal Register** of February 1, 2006 (71 FR 5200), we published a proposed rule (the February 2006 proposal) to amend § 203.22, which excludes certain activities from the sales restrictions in § 203.20. As proposed, § 203.22 would have provided a limited exclusion for registered blood establishments that qualify as health care entities. The February 2006 proposal, as a result, would have allowed certain registered blood establishments that qualify as health care entities to distribute blood derivatives. The proposal sought information about the functions of registered blood establishments to assist us in determining whether further modification of the December 1999 final rule would be warranted in the interest of public health. We also requested comments on whether the proposal should be 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. In addition, we sought comment on whether hemophilia treatment centers should be included within the scope of the exclusion.

After reviewing the comments on the February 2006 proposal, we have made several changes to the rule, as described in the following table:

TABLE 1.—PRINCIPAL CHANGES BETWEEN THE PROPOSED AND FINAL RULE

Proposed Rule	Final Rule
Exclusion would apply to 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.	Exclusion applies to a registered blood establishment that qualifies as a health care entity, as long as all of the health care services that the establishment provides are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem/progenitor cells or performing diagnostic testing of specimens provided that these specimens are tested together with routine donor testing.
Exclusion would apply to the sale, purchase, or trade of, or the offer to sell, purchase, or trade any blood derivative.	Exclusion applies to the sale, purchase, or trade of, or the offer to sell, purchase, or trade any: (1) Drug indicated for a bleeding or clotting disorder, or anemia; (2) blood collection container approved under section 505 of the act; or (3) drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative).
Exclusion did not apply to hemophilia treatment centers.	Exclusion applies to the sale, purchase, or trade of, or the offer to sell, purchase, or trade, by a comprehensive hemophilia diagnostic treatment center that is receiving a grant under section 501(a)(2) of the Social Security Act and that qualifies as a health care entity, any drug indicated for a bleeding or clotting disorder, or anemia, or any drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative).

We describe and respond to the comments on the February 2006 proposal in section II of this document. We grouped into comment categories those comments with similar types of issues. To make it easier to identify the comment category and our response, the word ''Comment,'' in parentheses, will appear before the comment category's description, and the word ''Response,'' in parentheses, will appear before our response. We have also numbered each comment category to help distinguish between different comment types. The number assigned to each comment category is purely for organizational purposes and does not signify the comment category's value or importance or the order in which a particular comment was received.

II. Comments on the February 2006 Proposal

We received several types of comments on the proposed rule.

(Comment 1) Some comments requested that the exclusion be expanded to allow registered blood establishments to distribute other drugs, in addition to blood derivatives, that are used to treat bleeding disorders. According to the comments, a number of blood centers in effect act as regional centers of transfusion medicine and as part of their core blood-related mission also supply their hospital customers with certain blood-related products that are not blood derivatives. Further, the

comments maintained that the current system is cost-effective whereby blood centers offer community hospitals the full range of blood-related products and trained personnel and expertise in handling those products. The comments contended that patients also benefit from blood centers' commitment to maintaining an adequate supply of blood-related products.

(Response) We agree that the exclusion should be expanded to allow registered blood establishments to distribute certain drugs in addition to blood derivatives and therefore have modified the final rule to include within the scope of the exclusion any:

- Drug indicated for a bleeding disorder,
- Drug indicated for a clotting disorder,
- Drug indicated for anemia,
- Blood collection container approved under section 505 of the act (21 U.S.C. 355), and
- Drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative).

(Comment 2) One comment stated that some blood centers, as part of their core blood-related mission, also supply their hospital customers with certain blood-related products not derived from human blood. For example, blood centers distribute recombinant erythropoietin, which is used to stimulate the production of red blood cells.

(Response) Under the final rule as revised, drugs indicated for anemia, such as erythropoiesis-stimulating agents, are subject to the exclusion in § 203.22(h).

(Comment 3) One comment, through a survey of blood centers, described drugs other than blood derivatives distributed by some blood centers. These drugs included TRASYLOL (aprotinin injection), STIMATE nasal spray (desmopressin acetate nasal spray), tetanus and diphtheria (Td) vaccine, and the rabies vaccines RABAVERT and IMOVAX.

(Response) The manufacturer of TRASYLOL (aprotinin) is removing the drug from the U.S. market due to safety concerns and therefore at this time access to TRASYLOL is limited to investigational use of the drug according to the procedures described in a special treatment protocol. Desmopressin acetate injection is indicated for treatment of certain types of blood disorders such as Hemophilia A and von Willebrand's disease (Type I). It is therefore included in the § 203.22(h) exclusion for any drug indicated for a bleeding or clotting disorder, or anemia. Desmopressin acetate nasal spray, however, is not indicated for a bleeding or clotting disorder, or anemia, and it is not a blood derivative (or a recombinant or synthetic form of a blood derivative), and therefore is not included within the exclusion in § 203.22(h).

Tetanus and diphtheria (Td) vaccine and rabies vaccines are not included within the exclusion in § 203.22(h) because they are not indicated for a bleeding or clotting disorder, or anemia, and they are not blood derivatives (or recombinant or synthetic forms of blood derivatives). Therefore, the further distribution by a registered blood establishment of Td vaccine and rabies vaccines is prohibited by § 203.20.

(Comment 4) One comment stated that as biotechnology advances, additional, partial substitutes for human blood are expected to become available. For example, the comment noted that hemoglobin-based oxygen carriers derived from bovine blood are in development. Blood centers would logically be involved in the supply chain of such drug products.

(Response) We agree that flexibility is needed to provide for the potential future development of drugs, such as blood substitutes, that would be used to treat bleeding disorders. For purposes of this discussion, the use of the term ''blood substitute'' refers to products such as hemoglobin-based oxygen carriers, which may partially or transitionally replace the function of blood elements. Our intent is that the exclusions in § 203.22(h) and (i) could apply to a blood substitute product that might be licensed or approved in the future.

(Comment 5) One comment suggested that hemophilia treatment centers should be included within the scope of the exclusion. According to the comment, hemophilia treatment centers currently play a critical role in the distribution of clotting factor to ensure the appropriate care of persons with hemophilia and related bleeding disorders. Thus, prohibiting hemophilia treatment centers from distributing clotting factor would have a tremendous detrimental effect on access to care for patients with hemophilia and related bleeding disorders.

(Response) We agree. We recognize the role of hemophilia treatment centers in ensuring the appropriate care of persons with hemophilia and related bleeding disorders. We have revised § 203.22(i) to exclude from the sales restrictions in § 203.20 the sale, purchase, or trade of, or the offer to sell, purchase, or trade, by a comprehensive hemophilia diagnostic treatment center that is receiving a grant under section 501(a)(2) of the Social Security Act[1] and that qualifies as a health care entity, any drug indicated for a bleeding or clotting disorder, or anemia; or any drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative).

(Comment 6) One comment stated that certain registered blood establishments can also be hemophilia treatment centers. According to the comment, at least two federally funded hemophilia treatment centers are also registered blood establishments. The comment expressed concern that, if these entities provide health care services unrelated to their activities as a registered blood establishment, they would not be eligible for the exclusion. The comment suggested the final rule should clarify that the health care services provided by a registered blood establishment that is also a hemophilia treatment center should be considered related to its activities as a registered blood establishment. The routine distribution of clotting factor by such an establishment would be prohibited if it were determined that the services it provides to persons with hemophilia are not considered related to its activities as a registered blood establishment.

(Response) We agree with the issue presented in this comment and have modified the final rule to add an exclusion (§ 203.22(i)) for comprehensive hemophilia diagnostic treatment centers receiving a grant under section 501(a)(2) of the Social Security Act. This exclusion does not require that the services provided by a comprehensive hemophilia diagnostic treatment center be related to its activities as a registered blood establishment. Thus, a comprehensive hemophilia diagnostic treatment center that is also a registered blood establishment may utilize the exclusion in § 203.22(i).

(Comment 7) One comment expressed concern that because blood centers also distribute blood bags containing anticoagulant, the presence of anticoagulants in the blood bags makes these products drugs and therefore subjects the blood bags to the provisions of the PDMA.

(Response) We agree with the concern expressed in this comment. A blood bag that contains an anticoagulant is regulated under the drug authorities. We do not want to interfere with current practices and potentially create

[1] Comprehensive hemophilia diagnostic treatment centers receive funding, as part of the National Hemophilia Program, through grants administered by the Department of Health and Human Services Health Resources and Services Administration under the authority provided in section 501(a)(2) of the Social Security Act (42 U.S.C. 701(a)(2)).

shortages of products collected in blood bags. Therefore, any blood collection container approved under section 505 of the act (*i.e.*, a blood bag containing an anticoagulant) is included in the exclusion in § 203.22(h).

(Comment 8) Some comments suggested the reference to ''blood derivatives'' should be modified to clarify that the exclusions cover all antihemophilic factor, both recombinant and plasma-derived.

(Response) We agree with these comments and have modified the exclusions in § 203.22(h) and (i) to clarify that the exclusions extend to recombinant or synthetic forms of blood derivatives.

(Comment 9) Some comments suggested the exclusion in § 203.22 should be broadened to include registered blood establishments that qualify as health care entities, as long as any health care services they provide are predominantly related to their activities as a registered blood establishment.

(Response) We believe that the substitution of the word ''predominantly'' for ''all'' in the phrase referring to the health care services that a registered blood establishment provides would make the provision too broad and would not provide the protections intended in the PDMA. However, we recognize that certain blood establishments, due to their specialized medical expertise, routinely collect, store and administer human hematopoietic stem/progenitor cells and conduct diagnostic testing of specimens concurrently with specimens undergoing routine donor testing. Our intent is to not interfere with the current practice of blood establishments to provide these specialized health care services. Therefore, instead of replacing ''all'' with ''predominantly,'' we extended the exclusion in § 203.22(h) to those registered blood establishments that collect, process, store, or administer human hematopoietic stem/progenitor cells or perform diagnostic testing of specimens provided that these specimens are tested together with specimens undergoing routine donor testing. Thus, a registered blood establishment that provides any health care services unrelated to its activities as a registered blood establishment is not eligible for the exclusion provided in the rule unless the unrelated health care services consist of collecting, processing, storing, or administering human hematopoietic stem/progenitor cells or performing diagnostic testing of specimens provided these specimens are tested together with specimens undergoing routine donor testing.

Examples of health care services that we view as related to registered blood establishments' activities and that would therefore allow these establishments to utilize the exclusion in § 203.22(h) include: Therapeutic hemapheresis, therapeutic phlebotomies, plasma exchange, transfusion services, and ordinary donor screening activities for donor suitability (*e.g.*, measuring a donor's temperature, blood pressure, and hematocrit or hemoglobin). We also consider preventive health care services intended to maintain a healthy donor population, such as administering influenza virus vaccines and testing the levels of prostate specific antigen and cholesterol in potential donors, to be related activities.

An example of a health care service that would prevent a registered blood establishment from utilizing the exclusion in § 203.22(h) is administering to a patient antibiotics intended to treat a respiratory infection unrelated to transfusion medicine. If a registered blood establishment engages in this activity, the establishment would not be permitted to distribute any drug indicated for a bleeding or clotting disorder, or anemia, any blood collection container approved under section 505 of the act, or any drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative). Without this limit on the types of health care services that may be provided, we are concerned the rule would encourage hospitals and other health care entities to register as blood establishments strictly to take advantage of this exclusion.

(Comment 10) One comment suggested the exclusion should extend to any distribution of drug products used in cellular and related biological therapies.

(Response) The reference to cellular and related biological therapy products goes beyond the scope of the proposed rule. Therefore, we decline to incorporate these products into the exclusions as part of this final rule.

III. Description of the Final Rule

This document modifies part 203 (21 CFR part 203) to allow a registered blood establishment[2] that provides certain health care services[3] and that also distributes certain drugs, to continue in both capacities. The distribution of these drug products, however, is permitted under this rule only if ''all of the health care services that the [registered blood] establishment provides are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem/progenitor cells or performing diagnostic testing of specimens provided that these specimens are tested together with specimens undergoing routine donor testing.'' This document also modifies part 203 to allow certain hemophilia treatment centers[4] that provide health care services and that also distribute certain drugs to continue in both capacities.

The final rule amends § 203.22, which contains exclusions from the sales restrictions in § 203.20. New paragraph (h) provides a limited exclusion for certain registered blood establishments that also qualify as health care entities. Under the exclusion, the sales restrictions in § 203.20 would not apply to the sale, purchase, or trade of (or the offer to sell, purchase, or trade) any: (1) Drug indicated for a bleeding or clotting disorder, or anemia; or (2) blood collection container approved under section 505 of the act; or (3) drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative), by a registered blood establishment that qualifies as a health care entity as long as all of the health care services that the establishment provides are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem/progenitor cells or performing diagnostic testing of specimens provided that these specimens are tested together with specimens undergoing routine donor testing.

For a registered blood establishment located within a hospital, such as a blood bank or transfusion service, we consider the registered blood establishment to be that part of the hospital that functions as a registered blood establishment and, for the purposes of this final rule, to be

[2] 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'' (21 CFR 607.3(c)). Owners or operators of establishments that engage in the manufacturing of blood products are required to register as described in 21 CFR 607.7(a).

[3] Health care services are provided by a health care entity defined in relevant part 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 any wholesale distributor.''

[4] The exclusion in the final rule extends to comprehensive hemophilia diagnostic treatment centers receiving grants under section 501(a)(2) of the Social Security Act.

included in the § 203.22(h) exclusion. If, however, on a case-by-case basis, the facts show that a registered blood establishment located in a hospital is taking advantage of the exclusion but is providing health care services beyond those specified in § 203.22(h), then that registered blood establishment is in violation of this final rule and the PDMA and may be subject to administrative or regulatory action, or criminal prosecution, for any such violation.

New § 203.22(i) provides a limited exclusion for certain hemophilia treatment centers that qualify as health care entities. Under the exclusion, the sales restrictions in § 203.20 would not apply to the sale, purchase, or trade of (or the offer to sell, purchase, or trade) any drug indicated for a bleeding or clotting disorder, or anemia, or any drug that is a blood derivative (or a recombinant or synthetic form or a blood derivative), by a comprehensive hemophilia diagnostic treatment center that is receiving a grant under section 501(a)(2) of the Social Security Act and that qualifies as a health care entity.

The exclusions in § 203.22(h) and (i) are intended to allow for the sale, purchase, trade of (or offer to sell, purchase, or trade) drugs related to the hematological needs of a patient related to bleeding, anemia, or hematological replacement therapies. These drugs include clotting factors such as Factor VIII, Factor IX, and von Willebrand Factor used to treat hemophilic disorders; pharmaceuticals such as tranexamic acid used to prevent bleeding from clot lysis; and, erythropoiesis stimulating agents used to treat anemia. Examples of drugs that are blood derivatives, which are included in the exclusions, are immune globulins, coagulation proteins, and human serum albumin. Recombinant and synthetic forms of blood derivatives, such as coagulation proteins and antihemophilic clotting factor, are also included in the exclusions. In addition, blood bags containing anticoagulant are covered by the exclusion's provision for blood collection containers approved under section 505 of the act.

The exclusions in § 203.22(h) and (i) apply only to a registered blood establishment (§ 203.22(h)) or a comprehensive hemophilia diagnostic treatment center (§ 203.22(i)), and not to other entities. These exclusions are narrow and apply only to certain registered blood establishments and comprehensive hemophilia diagnostic treatment centers that qualify as health care entities and that meet other specific criteria. These exclusions do not exempt any person or entity from the other requirements in part 203 *Prescription Drug Marketing* .

IV. Paperwork Reduction Act of 1995

This final 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.

V. Environmental Impact

The agency has determined under 21 CFR 25.30 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the 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 has concluded that the 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.

VII. Analysis of Impacts

FDA has examined the impacts of the final 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 final rule is not a significant regulatory action under 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 final rule will not have a significant economic impact on a substantial number of small entities.

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 $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

List of Subjects

21 CFR Part 203

Labeling, Prescription drugs, Reporting and recordkeeping 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, 21 CFR parts 203 and 205 are 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) and (i), a person cannot simultaneously be a ''health care entity'' and a retail pharmacy or wholesale distributor.

* * * * *

■ 3. Section 203.22 is amended by adding paragraphs (h) and (i) to read as follows:

§ 203.22 Exclusions.

* * * * *

(h) The sale, purchase, or trade of, or the offer to sell, purchase, or trade, by a registered blood establishment that qualifies as a health care entity any:

(1) Drug indicated for a bleeding or clotting disorder, or anemia;

(2) Blood collection container approved under section 505 of the act; or

(3) Drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative); as long as all of the health care services that the establishment provides are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem/progenitor cells or performing diagnostic testing of specimens provided that these specimens are tested together with specimens undergoing routine donor testing. Blood establishments relying on the exclusion in this paragraph must satisfy all other requirements of the act and this part applicable to a wholesale distributor or retail pharmacy.

(i) The sale, purchase, or trade of, or the offer to sell, purchase, or trade, by a comprehensive hemophilia diagnostic treatment center that is receiving a grant under section 501(a)(2) of the Social Security Act and that qualifies as a health care entity, any drug indicated for a bleeding or clotting disorder, or anemia, or any drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative). Comprehensive hemophilia diagnostic treatment centers relying on the exclusion in this paragraph must satisfy all other requirements of the act and this part applicable to a wholesale distributor or retail pharmacy.

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) and (i) of this chapter, a person cannot simultaneously be a ''health care entity'' and a retail pharmacy or wholesale distributor.

Dated: October 3, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–24050 Filed 10–8–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8073]

Income, Excise, and Estate and Gift Taxes; Effective Dates and Other Issues Arising Under the Employee Benefit Provisions of the Tax Reform Act of 1984; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to temporary regulations (TD 8073) that were published in the **Federal Register** on Tuesday, February 4, 1986 (51 FR 4312) relating to effective dates and certain other issues arising under sections 91, 223, and 511–561 of the Tax Reform Act of 1984. This action is necessary because of changes to the applicable tax law made by the Tax Reform Act of 1984. The temporary regulations will affect qualified employee benefit plans, welfare benefit funds and employees receiving benefits through such plans.

DATES: This correction is effective October 9, 2008, and is applicable after December 31, 1985.

FOR FURTHER INFORMATION CONTACT: Melissa A. D'Ambrose, (202) 622–6080 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations that are the subject of this document are under sections 72, 79, 125, 133, 402, 404, 419, 461, 463, 505, 512, and 1042 of the Internal Revenue Code.

Need for Correction

As published, temporary regulations (TD 8073) contain an error that may prove to be misleading and is in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

■ Accordingly, 26 CFR part 1 is corrected by making the following correcting amendment:

PART 1—INCOME TAXES

■ **Paragraph 1**. The authority citation for part 1 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2**. Section 1.512(a)–5T A–3: (b) is amended by revising the second sentence to read as follows:

§ 1.512(a)–5T Questions and answers relating to the unrelated business taxable income of organizations described in paragraphs (9), (17) or (20) of section 501(c) (temporary).

* * * * *

A–3: * * *

(b) * * * For purposes of section 512(a)(3)(B), member contributions include both employee contributions and employer contributions to the VEBA, SUB, or GLSO.

* * * * *

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

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DEPARTMENT OF DEFENSE

Office of the Secretary

[DOD–2007–OS–0025]

RIN 0790–AI08

32 CFR Part 112

Indebtedness of Military Personnel

AGENCY: Department of Defense.

ACTION: Final rule.

SUMMARY: This part contains uniform Department of Defense policies for indebtedness of military personnel. This updated rule contains editorial changes only as required for internal Department of Defense mandated reconsideration every five years.

DATES: *Effective Date:* This rule is effective November 10, 2008.

FOR FURTHER INFORMATION CONTACT: Lieutenant Colonel Tom Williams, Office of the Deputy Under Secretary of Defense for Program Integration, 4000 Defense Pentagon, Washington, DC 20301–4000.

SUPPLEMENTARY INFORMATION: The proposed rule was published on April 17, 2007 at 72 FR 19136. One editorial