classification subdivisions specified on such Report, or categories that are in accord with generally accepted account ing principles. Each person so registered shall prepare and keep current such records.

(b) Each applicant or registrant must make and keep as a record in accordance with § 1.31 formal computations of its adjusted net capital and of its minimum financial requirements pursuant to § 1.17 or the requirements of the designated self-regulatory organization to which it is subject as of the close of business each month. An applicant or registrant which is also registered as a securities broker or dealer with the Securities and Exchange Commission may meet the computation requirements of this paragraph (b) by completing the Statement of Financial and Operational Combined Uniform Single Report under the Securities Exchange Act of 1934, Part II or Part IIA. Such computations must be completed and made available for inspection by any representative of the National Futures Association, in the case of an applicant, or of the Commission or designated self-regulatory organization, if any, in the case of a registrant, within 10 business days after the date for which the computations are made, commencing the first monthend after the date the application for registration is filed.

* * * * *

6. Section 1.52 is amended by revising paragraph (a) to read as follows:

§ 1.52 Self-regulatory organization adoption and surveillance of minimum financial requirements.

(a) Each self-regulatory organization must adopt, and submit for Commission approval, rules prescribing minimum financial and related reporting requirements for all its members who are registered futures commission merchants. Each self-regulatory organization other than a contract market must adopt, and submit for Commission approval, rules prescribing minimum financial and related reporting requirements for all its members who are registered introducing brokers. Each contract market which elects to have a category of membership for introducing brokers must adopt, and submit for Commission approval, rules prescribing minimum financial and related reporting requirements for all its members who are registered introducing brokers. Each self-regulatory organization shall submit for Commission approval any modification or other amendments to such rules. Such requirements must be the same as, or more stringent than, those contained in §§ 1.10 and 1.17 of this part and the definition of adjusted net capital must be the same as that prescribed in § 1.17(c) of this part: *Provided, however,* A designated self-regulatory organization may permit its member registrants which are registered with the Securities and Exchange Commission as securities brokers or dealers to file (in accordance with § 1.10(h) of this part) a copy of their Financial and Operational Combined Uniform Single Report under the Securities Exchange Act of 1934, Part II or Part IIA, in lieu of Form 1–FR: And, provided further, A designated self-regulatory organization may permit its member introducing brokers to file a Form 1–FR–IB in lieu of a Form 1–FR–FCM.

* * * * *

PART 3—REGISTRATION

7. The authority citation for Part 3 is revised to read as follows:

Authority: 7 U.S.C. 1a, 2, 4, 4a, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6k, 6m, 6o, 6p, 8, 9, 9a, 12, 12a, 13b, 13c, 16a, 18, 19, 21, 23; 5 U.S.C. 552, 552b.

Subpart A—Registration

8. Section 3.33 is amended by revising paragraph (c)(1) to read as follows:

§ 3.33 Withdrawal from registration.

* * * * *

(c)(1) Where a futures commission merchant or an introducing broker which is not operating pursuant to a guarantee agreement is requesting withdrawal from registration in that capacity and the basis for withdrawal under paragraph (a)(1) of this section is that it has ceased engaging in activities requiring registration, the request for withdrawal must be accompanied by a Form 1–FR–FCM or a Form 1–FR–IB, respectively, which contains the information specified in § 1.10(d)(1) of this chapter as of a date not more than 30 days prior to the date of the withdrawal request: *Provided, however,* That if such registrant is also registered with the Securities and Exchange Commission as a securities broker or dealer, it may file a copy of its Financial and Operational Combined Uniform Single Report under the Securities Exchange Act of 1934, Part II or Part IIA (in accordance with § 1.10(h) of this chapter), in lieu of Form 1–FR–FCM or Form 1–FR–IB. Any financial report submitted pursuant to this paragraph (c)(1) must contain the information specified in § 1.10(d)(1) of this chapter as of a date not more than 30 days prior to the date of the withdrawal request.

* * * * *

PART 145—COMMISSION RECORDS AND INFORMATION

9. The authority citation for Part 145 continues to read as follows:

Authority: Pub. L. 89–554, 80 Stat. 383, Pub. L. 90–23, 81 Stat. 54, Pub. L. 93–502, 88 Stat. 1561–1564 (5 U.S.C. 552); Sec. 101(a), Pub. L. 93–463, 88 Stat. 1389 (5 U.S.C. 4a(j)); Pub. L. 99–570, unless otherwise noted.

§ 145.5 [Amended]

10. Section 145.5 is amended by removing and reserving paragraph (d)(1)(i)(G).

PART 147—OPEN COMMISSION MEETINGS

11. The authority citation for Part 147 continues to read as follows:

Authority: Sec. 3(a), Pub. L. 94–409, 90 Stat. 1241 (5 U.S.C. 552b); Sec. 101(a)(11), Pub. L. 93–463, 88 Stat. 1391 (7 U.S.C. 4a(j)(Supp. V 1975)), unless otherwise noted.

§ 147.3 [Amended]

12. Section 147.3 is amended by removing and reserving paragraph (b)(4)(i)(A)(*7*).

Issued in Washington, D.C. on February 20, 1996 by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 96–4236 Filed 2–23–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 96N–0002]

''Draft Document Concerning the Regulation of Placental/Umbilical Cord Blood Stem Cell Products Intended for Transplantation or Further Manufacture into Injectable Products;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Availability of draft document.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Draft Document Concerning the Regulation of Placental/Umbilical Cord Blood Stem Cell Products Intended for Transplantation or Further Manufacture into Injectable Products (December 1995).'' This draft document is intended to identify an approach that FDA believes is appropriate for the regulation of placental/umbilical cord blood stem

cell products for transplantation and to provide an opportunity for interested persons to submit written comments on the draft document. This document is in response to numerous inquiries regarding the agency's regulatory approach to cord blood stem cell products. The draft document was distributed at the public workshop held on December 13, 1995, as announced in the Federal Register of November 24, 1995 (60 FR 58088). FDA has since made editorial changes to the draft document but the content and technical information remains unchanged.

DATES: Written comments by April 26, 1996.

ADDRESSES: Submit written requests for single copies of the draft document entitled ''Draft Document Concerning the Regulation of Placental/Umbilical Cord Blood Stem Cell Products for Transplantation or Further Manufacture into Injectable Products'' to the Division of Congressional and Public Affairs (HFM–44), Office of Communication, Training and Manufacturers Assistance, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, or call FDA's automated information system at 1–800–835–4709. Send one self-addressed adhesive label to assist that office in processing your requests. Persons with access to the INTERNET may request the document be sent by return E-mail by sending a message to ''CORDSTEM@A1..CBER.FDA.GOV''. The draft document may also be obtained through INTERNET via File Transfer Protocol (FTP). Requesters should connect to the Center for Drug Evaluation and Research (CDER) FTP using the FTP. The Center for Biologics Evaluation and Research (CBER) documents are maintained in a subdirectory called CBER on the server, ''CDVS2.CDER.FDA.GOV'' (150.148.24.202). The ''READ.ME'' file in that subdirectory describes the available documents, which may be available as an ASCII text file (*.TXT), or WordPerfect 5.1 document (*.w51), or both. A sample dialogue for obtaining the READ.ME file with a test based FTP program would be:

FTP CDVS2.CBER.FDA.GOV
LOGIN ANONYMOUS
<ANY PASSWORD> <''YOUR EMAIL ADDRESS''>
BINARY
CD CBER
GET READ.ME
EXIT

The draft document may also be obtained by calling the CBER FAX information system (FAX-On-Demand) at 1–800–835–4709 from a touch tone telephone. Submit written comments on the draft document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of all comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft document and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Introduction

Traditional bone marrow transplantation, involving the extraction of bone marrow by aspiration from bone cavities and processing by density gradient centrifugation, is increasingly being supplanted by novel sources of stem cells and biotechnologic procedures to purify and expand hematopoietic stem cells. Human cord blood, which is enriched with pluripotent hematopoietic stem cells, has recently emerged as an alternative source of hematopoietic stem cells for patients who are unable to obtain stem cells from allogeneic donors. Although availability of cord blood stem cells may reduce some constraints on bone marrow transplantation, the ultimate safety and efficacy of cord blood stem cell transplantation has yet to be determined.

Recently, the agency has received numerous inquiries regarding the regulatory approach to cord blood stem cell products. Cord blood stem cells for transplantation in autologous or allogeneic recipients is an emerging area with complex medical issues, including issues raised by the banking of such cells for possible future transplantation. Unlike bone marrow donors who are at least several years old with a medical history, cord blood is obtained from a newborn donor without an established medical history. Existing FDA statutory authorities apply to these new products and allow FDA to see that areas such as quality control, quality assurance, safety, purity, potency, and efficacy are appropriately addressed prior to marketing.

FDA is announcing the availability of a draft document that includes discussions of the following: (1) The applicable legal authorities in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act; (2) FDA's approach to the regulation of human cord blood stem cells intended for transplantation; (3) FDA's approach to the regulation of cord blood stem cells as source material for further manufacture; (4) FDA's approach to the regulation of ancillary products used for production of cord blood stem cells; and (5) a request for public comments on the regulatory approach.

II. Comments

FDA is providing for comment the draft document prepared by the Office of Blood Research and Review and the Office of Therapeutics Research and Review in CBER. FDA does not intend the draft document to be all-inclusive. This draft document does not bind FDA and does not create or confer any rights, privileges, or benefits on or for any person.

FDA recognizes that cord blood stem cell products used for hematologic transplantation constitute a new and emerging scientific area. FDA will review and consider written comments on the regulatory approach set forth in the draft document. FDA specifically invites public comment on the approach for regulation of cord blood stem cells as source material for further manufacture and for regulation of ancillary products used in the production of cord blood stem cells, as discussed in the draft document.

Interested persons may, on or before April 26, 1996, submit to the Dockets Management Branch (address above) comments on the draft document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft document and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FDA will consider any written comments received in determining whether amendments to, or revisions of, the document are warranted.

Dated: February 13, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–4065 Filed 2–23–96; 8:45 am]

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