

Rasco Trust, DeWitt, Arkansas (Nancy Ferguson Rasco and DeWitt Bank & Trust as co-trustees); the Rebecca F. Ehrlicher Trust, DeWitt, Arkansas (Rebecca Ferguson Ehrlicher and DeWitt Bank & Trust as co-trustees); the Charles W. Rasco III Marital Trust (DeWitt Bank & Trust as trustee); and the Elmer Ferguson Farms, Inc., DeWitt, Arkansas; to retain voting shares of DBT Financial Corporation, DeWitt, Arkansas, and thereby indirectly acquire additional voting shares of DeWitt Bank and Trust Company, DeWitt, Arkansas.

Board of Governors of the Federal Reserve System, December 15, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E5-7555 Filed 12-19-05; 8:45 am]

BILLING CODE 6210-01-S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. E5-7262) published on page 73747 of the issue for Tuesday, December 13, 2005.

Under the Federal Reserve Bank of New York heading, the entry for Community Partners Bancorp, Middletown, New Jersey, is revised to read as follows:

A. Federal Reserve Bank of New York (Jay Bernstein, Bank Supervision Officer) 33 Liberty Street, New York, New York 10045-0001:

1. *Community Partners Bancorp*, Middletown, New Jersey; to become a bank holding company by acquiring 100 percent of the voting shares of Two River Community Bank, Middletown, New Jersey, and The Town Bank, Westfield, New Jersey.

Comments on this application must be received by January 6, 2006.

Board of Governors of the Federal Reserve System, December 15, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E5-7556 Filed 12-19-05; 8:45 am]

BILLING CODE 6210-01-S

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission ("FTC" or "Commission").

ACTION: Notice.

SUMMARY: The information collection requirements described below will be submitted to the Office of Management and Budget ("OMB") for review, as required by the Paperwork Reduction Act ("PRA") (44 U.S.C. 3501-3520). The FTC is seeking public comments on its proposal to extend through December 31, 2008 the current PRA clearances for information collection requirements contained in four product labeling rules enforced by the Commission. Those clearances expire on December 31, 2005.

DATES: Comments must be received on or before January 19, 2006.

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to "Apparel Rules: FTC File No. P948404" to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope and should be mailed or delivered, with two complete copies, to the following address: Federal Trade Commission/Office of the Secretary, Room H-135 (Annex J), 600 Pennsylvania Avenue, NW., Washington, DC 20580. Because paper mail in the Washington area and at the Commission is subject to delay, please consider submitting your comments in electronic form, (in ASCII format, WordPerfect, or Microsoft Word) as part of or as an attachment to email messages directed to the following email box: paperworkcomment@ftc.gov. However, if the comment contains any material for which confidential treatment is requested, it must be filed in paper form, and the first page of the document must be clearly labeled "Confidential."¹ Comments should also be submitted to: Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission. Comments should be submitted via facsimile to (202) 395-6974 because U.S. Postal Mail is subject to lengthy delays due to heightened security precautions.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments will be considered by the Commission and will be available to the public on the FTC website, to the extent practicable, at <http://www.ftc.gov>.

¹ Commission Rule 4.2(d), 16 CFR 4.2(d). The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. See Commission Rule 4.9(c), 16 CFR 4.9(c).

As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy at <http://www.ftc.gov/ftc/privacy.htm>.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information requirements should be addressed as follows:

For the Fur Act Regulations, Wool Act Regulations, and Textile Act Regulations, contact Carol Jennings, Attorney, Enforcement Division, Bureau of Consumer Protection 600 Pennsylvania Ave., NW., Washington, DC 20580, (202) 326-2996.

For the Care Labeling Rule, contact Connie Vecellio, Attorney, Enforcement Division, Bureau of Consumer Protection, 600 Pennsylvania Ave., NW., Washington, DC 20580, (202) 326-2996.

SUPPLEMENTARY INFORMATION: On September 28, 2005, the FTC sought comment on the information collection requirements associated with regulations under the Fur Act, 16 CFR Part 301 (OMB Control Number 3084-0099); regulations under the Wool Act, 16 CFR Part 300 (OMB Control Number 3084-0100); regulations under the Textile Act, 16 CFR Part 303 (OMB Control Number 3084-0101); and the Care Labeling Rule, 16 CFR 423 (OMB Control Number 3084-0103). See 70 FR 56692. No comments were received. Pursuant to the OMB regulations that implement the PRA (5 CFR Part 1320), the FTC is providing this second opportunity for public comment while seeking OMB approval to extend the existing paperwork clearance for the rules. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before January 19, 2006.

Staff's burden estimates for the four rules in question are based on data from the Bureau of Census, U.S. Customs and International Trade Commission, the Department of Labor, and data or other input from industry sources. The relevant information collection requirements within these rules and corresponding burden estimates follow.

1. Regulations Under the Fur Products Labeling Act, 15 U.S.C. 69 et seq. ("Fur Act"), 16 CFR Part 301 (OMB Control Number: 3084-0099)

The Fur Act prohibits the misbranding and false advertising of fur products. The Fur Act Regulations, 16

CFR 301, establish disclosure requirements that assist consumers in making informed purchasing decisions, and recordkeeping requirements that assist the Commission in enforcing these regulations. The Regulations also provide a procedure for exemption from certain disclosure provisions under the Fur Act.

Estimated annual hours burden: 168,000 hours, rounded to the nearest thousand (54,080 hours for recordkeeping + 113,633 hours for disclosure).

Recordkeeping: The Regulations require that retailers, manufacturers, processors, and importers of furs and fur products keep certain records in addition to those they may keep in the ordinary course of business. Staff estimates that 1,300 retailers incur an average recordkeeping burden of about 13 hours per year (16,900 hours total); 115 manufacturers and fur processors combined incur an average recordkeeping burden of about 52 hours per year (5,980 total); and 1,200 importers of furs and fur products incur an average recordkeeping burden of 26 hours per year (31,200 hours total). The

combined recordkeeping burden for the industry is approximately 54,080 hours annually.

Disclosure: Staff estimates that 1,400 respondents (100 manufacturers + 1,300 retail sellers of fur garments) each require an average of 20 hours per year to determine label content (28,000 hours total), and an average of five hours per year to draft and order labels (7,000 hours total). Staff estimates that the total number of garments subject to the fur labeling requirements is approximately 3,000,000.² Staff estimates that for approximately half of these garments, labels are attached manually, requiring approximately two minutes per garment for a total of 50,000 hours annually. For the remaining 1,500,000, the process of attaching labels is semi-automated and requires an average of approximately two seconds per item, for a total of 1,000 hours (rounded to the nearest thousand). Thus, the total burden for attaching labels is 51,000 hours, and the total burden for labeling garments is 86,000 hours per year.

Staff estimates that the incremental burden associated with the Regulations' invoice disclosure requirement, beyond

the time that would be devoted to preparing invoices in its absence, is approximately 30 seconds per invoice.³ The invoice disclosure requirement applies to fur garments, which are generally sold individually, and fur pelts, which are generally sold in groups of at least 50, on average. Assuming invoices are prepared for sales of 3,000,000 garments and 160,000 groups (an estimated 8 million pelts ÷ 50) each of imported and domestic pelts, the invoice disclosure requirement entails an estimated total burden of 26,333 hours.

Staff estimates that the Regulations' advertising disclosure requirements impose an average burden of one hour per year for each of the approximately 1,300 domestic fur retailers, or a total of 1,300 hours.

Thus, staff estimates the total disclosure burden to be approximately 113,633 hours (86,000 hours for labeling + 26,333 hours for invoices + 1,300 hours for advertising).

Estimated annual cost burden: \$2,153,000, rounded to the nearest thousand (solely relating to labor costs).

Task	Hourly rate	Burden hours	Labor cost
Determine label content	\$ 20.00	28,000	\$560,000
Draft and order labels	13.00	7,000	91,000
Attach labels	4 8.50	51,000	433,500
Invoice disclosures	13.00	26,333	342,329
Prepare advertising disclosures	18.00	1,300	23,400
Recordkeeping	13.00	54,080	703,040
Total			2,153,269

⁴ Per industry sources, most fur labeling is done in the U.S., and this rate is reflective of an average domestic hourly wage for such tasks. Conversely, attaching labels with regard to the others regulations discussed herein is mostly performed by foreign labor, as detailed in note 5.

² The total number of fur garments, fur-trimmed garments, and fur accessories is estimated to be approximately 3,500,000, based on International Trade Commission data. Of that number, approximately 500,000 items are estimated to be

exempt from the labeling requirements pursuant to 16 CFR 301.39 (items where either the cost of the fur trim to the manufacturer or the manufacturer's selling price for the finished product is less than \$150 are exempt).

³ The invoice disclosure burden for PRA purposes excludes the time that respondents would spend for invoicing, apart from the Fur Act Regulations, in the ordinary course of business. See 5 CFR 1320.3(b)(2).

Staff believes that there are no current start-up costs or other capital costs associated with the Regulations. Because the labeling of fur products has been an integral part of the manufacturing process for decades, manufacturers have in place the capital equipment necessary to comply with the Regulations' labeling requirements. Industry sources indicate that much of the information required by the Fur Act and its implementing Regulations would be included on the product label even absent the regulations. Similarly, invoicing, recordkeeping, and advertising disclosures are tasks performed in the ordinary course of business so that covered firms would incur no additional capital or other non-labor costs as a result of the Act or the Regulations.

2. Regulations Under the Wool Products Labeling Act, 15 U.S.C. 68 et seq. ("Wool Act"), 16 CFR Part 300 (OMB Control Number: 3084-0100)

The Wool Act prohibits the misbranding of wool products. The Wool Act Regulations, 16 CFR 300, establish disclosure requirements that assist consumers in making informed purchasing decisions and recordkeeping requirements that assist the Commission in enforcing the Regulations.

Estimated annual hours burden: 407,000 hours, rounded to the nearest thousand (80,000 recordkeeping hours + 326,667 disclosure hours).

Recordkeeping: Staff estimates that approximately 4,000 wool firms are subject to the Regulations' recordkeeping requirements. Based on an average annual burden of 20 hours per firm, the total recordkeeping burden is 80,000 hours.

Disclosure: Approximately 8,000 wool firms, producing or importing about 500,000,000 wool products annually, are subject to the Regulations'

disclosure requirements. Staff estimates the burden of determining label content to be 15 hours per year per respondent, or a total of 120,000 hours, and the burden of drafting and ordering labels to be 5 hours per respondent per year, or a total of 40,000 hours. Staff believes that the process of attaching labels is now fully automated and integrated into other production steps for about 40 percent of all affected products. For the remaining 300,000,000 items (60 percent of 500,000,000), the process is semi-automated and requires an average of approximately two seconds per item, for a total of 166,667 hours per year. Thus, the total estimated annual burden for all respondents is 326,667 hours. Staff believes that any additional burden associated with advertising disclosure requirements would be minimal (less than 10,000 hours) and can be subsumed within the burden estimates set forth above.

Estimated annual cost burden: \$4,460,000, rounded to the nearest thousand (solely relating to labor costs).

Task	Hourly rate	Burden hours	Labor cost
Determine label content	\$20.00	120,000	\$2,400,000
Draft and order labels	13.00	40,000	520,000
Attach labels	⁵ 3.00	166,667	500,001
Recordkeeping	13.00	80,000	1,040,000
Total			4,460,001

⁵ For products that are imported, this work generally is done in the country where they are manufactured. According to information compiled by an industry trade association using data from the International Trade Commission, the U.S. Customs Service, and the U.S. Census Bureau, approximately 90% of apparel and other textile products used in the United States is imported. With the remaining 10% attributable to U.S. production at an approximate domestic hourly wage of \$8.50 to attach labels, staff has calculated a weighted average hourly wage of \$3 per hour attributable to U.S. and foreign labor combined. The estimated percentage of imports supplied by particular countries is based on trade data for 2001 compiled by the Office of Textiles and Apparel, International Trade Administration, U.S. Department of Commerce. Wages in major textile exporting countries, factored into the above hourly wage estimate, were based on data published in February 2000 by the U.S. Department of Labor, Bureau of International Labor Affairs (See "Wages, Benefits, Poverty Line, and Meeting Workers' Needs in the Apparel and Footwear Industries of Selected Countries," Table I-2: "Prevailing or Average Wages in the Manufacturing Sector and in the Footwear and Apparel Industries in Selected Countries, Latest Available Year").

Staff believes that there are no current start-up costs or other capital costs associated with the Regulations. Because the labeling of wool products has been an integral part of the manufacturing process for decades, manufacturers have in place the capital equipment necessary to comply with the Regulations. Based on knowledge of the industry, staff believes that much of the information required by the Wool Act and its implementing regulations would be included on the product label even absent their requirements. Similarly, recordkeeping and advertising disclosures are tasks performed in the ordinary course of business so that covered firms would incur no additional capital or other non-labor costs as a result of the Regulations.

3. Regulations Under the Textile Fiber Products Identification Act, 15 U.S.C. 70 et seq. ("Textile Act"), 16 CFR Part 303 (OMB Control Number: 3084-0101)

The Textile Act prohibits the misbranding and false advertising of textile fiber products. The Textile Act Regulations, 16 CFR 303, establish disclosure requirements that assist consumers in making informed purchasing decisions, and recordkeeping requirements that assist the Commission in enforcing the Regulations. The Regulations also contain a petition procedure for requesting the establishment of generic names for textile fibers.⁵

Estimated annual hours burden: approximately 8,011,000 hours, rounded to the nearest thousand (600,000 recordkeeping hours + 7,411,111 disclosure hours).

Recordkeeping: Staff estimates that approximately 24,000 textile firms are subject to the Textile Regulations' recordkeeping requirements. Based on an average burden of 25 hours per firm, the total recordkeeping burden is 600,000 hours.

Disclosure: Approximately 32,000 textile firms, producing or importing about 19.9 billion textile fiber products annually, are subject to the Regulations' disclosure requirements.⁶ Staff

⁶ The apparent consumption of garments in the U.S. in 2004 was 18.4 billion. Staff estimates that 1 billion garments are exempt from the Textile Act (*i.e.*, any kind of headwear and garments made from something other than a textile fiber product, such as leather) or are subject to a special exemption for hosiery products sold in packages where the label information is contained on the package. Based on available data, staff estimates that an additional 3 billion household textile products (non-garments, such as sheets, towels, blankets) were consumed.

estimates the burden of determining label content to be 20 hours per year per respondent, or a total of 640,000 hours and the burden of drafting and ordering labels to be 5 hours per respondent per year, or a total of 160,000 hours. Staff believes that the process of attaching labels is now fully automated and integrated into other production steps

for about 40 percent of all affected products. For the remaining 11.9 billion items (60 percent of 19.9 billion), the process is semi-automated and requires an average of approximately two seconds per item, for a total of 6,611,111 hours per year. Thus, the total estimated annual burden for all respondents is 7,411,111 hours. Staff believes that any

additional burden associated with advertising disclosure requirements or the filing of generic fiber name petitions would be minimal (less than 10,000 hours) and can be subsumed within the burden estimates set forth above.

Estimated annual cost burden: \$42,513,000, rounded to the nearest thousand (solely relating to labor costs).

Task	Hourly rate	Burden hours	Labor cost
Determine label content	\$ 20.00	640,000	\$12,800,000
Draft and order labels	13.00	160,000	2,080,000
Attach labels	⁷ 3.00	6,611,111	19,833,333
Recordkeeping	13.00	600,000	7,800,000
Total			42,513,333

⁷ See note 5.

Staff believes that there are no current start-up costs or other capital costs associated with the Regulations. Because the labeling of textile products has been an integral part of the manufacturing process for decades, manufacturers have in place the capital equipment necessary to comply with the Regulations' labeling requirements. Industry sources indicate that much of the information required by the Textile Act and its implementing rules would be included on the product label even absent their requirements. Similarly, recordkeeping, invoicing, and advertising disclosures are tasks performed in the ordinary course of business so that covered firms would incur no additional capital or other non-labor costs as a result of the Regulations.

4. The Care Labeling Rule, 16 CFR Part 423 (OMB Control Number: 3084-0103)

The Care Labeling Rule, 16 CFR Part 423, requires manufacturers and

importers to attach a permanent care label to all covered textile clothing in order to assist consumers in making purchase decisions and in determining what method to use to clean their apparel. Also, manufacturers and importers of piece goods used to make textile clothing must provide the same care information on the end of each bolt or roll of fabric.

Estimated annual hours burden: 6,889,000 hours, rounded to the nearest thousand (solely relating to disclosure⁸).

Staff estimates that approximately 24,700 manufacturers or importers of textile apparel, producing about 17.4 billion textile garments annually, are subject to the Rule's disclosure requirements. The burden of developing proper care instructions may vary greatly among firms, primarily based on the number of different lines of textile garments introduced per year that require new or revised care instructions.

Staff estimates the burden of determining care instructions to be 43 hours each year per respondent, for a cumulative total of 1,062,100 hours. Staff further estimates that the burden of drafting and ordering labels is 2 hours each year per respondent, for a total of 49,400 hours. Staff believes that the process of attaching labels is fully automated and integrated into other production steps for about 40 percent of the approximately 17.4 billion garments that are required to have care instructions on permanent labels.⁹ For the remaining 10.4 billion items (60 percent of 17.4 billion), the process is semi-automated and requires an average of approximately two seconds per item, for a total of 5,777,778 hours per year. Thus, the total estimated annual burden for all respondents is 6,889,278 hours.

Estimated annual cost burden: \$39,218,000, rounded to the nearest thousand (solely relating to labor costs).

Task	Hourly rate	Burden hours	Labor cost
Determine care instructions	\$20.00	1,062,100	\$21,242,000
Draft and order labels	13.00	49,400	642,200
Attach labels	¹⁰ 3.00	5,777,778	17,333,334
Total			39,217,534

¹⁰ See note 5.

Staff believes that there are no current start-up costs or other capital costs associated with the Rule. Because the labeling of textile products has been an integral part of the manufacturing

process for decades, manufacturers have in place the capital equipment necessary to comply with the Rule's labeling requirements. Based on knowledge of the industry, staff believes

that much of the information required by the Rule would be included on the

However, approximately .5 billion of all of these combined products (garments and non-garments) are subject to the Wool Products Labeling Act, not the Textile Fiber Products Identification Act, because they contain some amount of wool. Thus, the estimated net total products subject to the Textile Fiber Products Identification Act is 19.9 billion.

⁸ The Care Labeling Rule imposes no specific recordkeeping requirements. Although the Rule requires manufacturers and importers to have reliable evidence to support the recommended care instructions, companies may provide as support current technical literature or rely on past experience.

⁹ About 1 billion of the 18.4 billion garments produced annually are either not covered by the Care Labeling Rule (gloves, hats, caps, and leather, fur, plastic, or leather garments) or are subject to an exemption that allows care instructions to appear on packaging (hosiery).

product label even absent those requirements.

William Blumenthal,
General Counsel.

[FR Doc. E5-7531 Filed 12-19-05; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Occupational Health and Safety Research, Program Announcement 04038 and Small Grants in Occupational Safety and Health, Program Announcement 04021

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Occupational Health and Safety Research, Program Announcement 04038 and Small Grants in Occupational Safety and Health, Program Announcement 04021.

Time and Date: 1 p.m.-3 p.m., January 13, 2006 (Closed).

Place: National Institute for Occupational Safety and Health, CDC, 1600 Clifton Road, NE, Mailstop E-74, Atlanta, GA 30333 Telephone Number (404) 498-2582.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters To Be Considered: The meeting will include the review, discussion, and evaluation of applications received in response to: Occupational Health and Safety Research, Program Announcement 04038 and Small Grants in Occupational Safety and Health, Program Announcement 04021.

Contact Person For More Information: Charles Rafferty, Ph.D., Scientific Review Administrator, National Institute for Occupational Safety and Health, CDC, 1600 Clifton Road, NE., Mailstop E-74, Atlanta, GA 30333, Telephone Number (404) 498-2582. The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: December 13, 2005.

Alvin Hall,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E5-7550 Filed 12-19-05; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of Supplemental New Animal Drug Application; Tilmicosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The approved NADA provides for the veterinary prescription use of an injectable solution of tilmicosin phosphate for respiratory disease in cattle and sheep. This supplemental NADA adds user safety information to product labeling.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 140-929 for MICOTIL 300 (tilmicosin phosphate), an injectable solution available by veterinary prescription for use in the treatment and control of respiratory disease in cattle and in the treatment of respiratory disease in sheep. This supplemental NADA adds user safety information to product labeling related to the mechanism of toxicity and medical intervention. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(i)) and part 514 (21 CFR part 514) in §§ 514.105(a) and 514.106(a), the Center for Veterinary Medicine is providing notice that this supplemental NADA is approved as of December 2, 2005. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and § 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) 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.

Dated: December 8, 2005.

Bernadette Dunham,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 05-24269 Filed 12-19-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0485]

Regulatory Process for Pediatric Mechanical Circulatory Support Devices (Ventricular Assist Devices)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: Regulatory Process for Pediatric Mechanical Circulatory Support Devices (Ventricular Assist Devices). The topics of discussion are the agency's activities regarding the regulation and approval of circulatory support devices used for temporary support in pediatric patients.

Date and Time: The public meeting will be held on January 20, 2006, from 9 a.m. to 12 p.m. The agency is requiring registration by December 30, 2005.

Location: The public meeting will be held at the Center for Devices and Radiological Health, rm. 20B, 9200 Corporate Blvd., Rockville, MD 20850.

Contact: Eric Chen, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., 301-443-8262, ext. 146, e-mail: eac@cdrh.fda.gov, or Michael Berman (HFZ-170), 12725 Twinbrook Pkwy., 301-827-4744, e-mail: mrb@cdrh.fda.gov. If you need special accommodations due to a disability, please contact Eric Chen, at least 7 days in advance of the meeting.

Registration: There is no fee to attend the workshop; however, because space is limited, registration is required. Please submit registration information (including name, title, firm name, address, e-mail address, telephone number, and fax number) by December 30, 2005 (see *Contact*). Background information for the workshop will be