place where the review will occur, and other details.

Petitioners may, at any time on or before August 7, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 20, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–17678 Filed 7–7–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0274]

Perclose, Inc.; Premarket Approval of Prostar® Percutaneous Vascular Surgical (PVS) System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Perclose, Inc., Menlo Park, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Prostar® Percutaneous Vascular Surgical (PVS) System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of April 30, 1997, of the approval of the application.

DATES: Petitions for administrative review by August 7, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Christopher M. Sloan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–8243.

SUPPLEMENTARY INFORMATION: On November 26, 1996, Perclose, Inc., Menlo Park, CA 94025, submitted to CDRH an application for premarket approval of Prostar® PVS System. The Prostar® PVS System consists of the Prostar® PVS Device (9 and 11 French sizes) and the following accessories: A Prostar® Pre-Dilator (9 and 11 French sizes), a Perclose® Knot Pusher, a Prostar® Transition Guidewire, and a Perclose® Arterial Tamper. The device is a vascular hemostasis device and is indicated for the percutaneous delivery of sutures for closing the common femoral artery access site and reducing the time to hemostasis and ambulation (time-to-standing) of patients who have undergone interventional procedures using 8 and 11 French sheaths.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On April 30, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 7, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 17, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–17679 Filed 7–7–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0192]

Revised Form FDA 356h, Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised Form FDA 356h entitled ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use.'' This revised form is intended to be used by applicants for a wide range of products regulated by the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) under the Public Health Service Act (the

PHS Act) and the Federal Food, Drug, and Cosmetic Act (the act). The revised form is also intended to standardize the application form, to reduce the time required to prepare applications, and to expedite review by FDA staff. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives, and is intended to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments may be submitted at any time. Applicants submitting new drug applications (NDA's), abbreviated new drug applications (ANDA's), abbreviated antibiotic drug applications (AADA's), applications for products specified in § 601.2(c) (21 CFR 601.2(c)), or for autologous somatic cell therapy products will be required to use revised Form 356h beginning January 8, 1998.

ADDRESSES:

CBER Information: Submit written requests for single copies of the revised Form FDA 356h to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448 . Send one self-addressed adhesive label to assist that office in processing your requests. The form may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the Fax Information System at 1–888–CBER–FAX or 301–827–3844.

CDER Information: Submit written requests for single copies of the revised Form FDA 356h to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573. Send one self-addressed adhesive label to assist that office in processing your request.

Submit written comments and requests for single copies of the revised Form FDA 356h to the Dockets Managements Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised Form FDA 356h.

FOR FURTHER INFORMATION CONTACT:

CBER: Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0381.

CDER: Jean A. Yager, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5480.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the revised Form FDA 356h, ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use.'' Form FDA 356h, dated October 1993, has been revised to create the new harmonized Form 356h that eventually will replace 20 application forms for licensed products regulated by CBER and former Form FDA 356h, dated October 1993, that was used for products regulated by CDER. As outlined in the President's November 1995, National Performance Review ''Reinventing the Regulation of Drugs Made From Biotechnology,'' FDA will use a single harmonized application form for all drug and licensed biological products. FDA subsequently developed a draft form that was made available for public comment in the **Federal Register** of October 1,1996 (61 FR 51285). Comments were received and considered and then revisions were made to the form based on some of the comments. A notice of request for comment to the Office of Management and Budget (OMB) on this information gathering was published in the **Federal Register** of March 13, 1997 (62 FR 11899). This information collection requirement was approved and assigned OMB control No. 0910–0338. The expiration date for this approval is April 30, 2000. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Currently, CBER uses three establishment license application forms: Form FDA 3210, ''Application for Establishment License for Manufacture of Biological Products;'' Form FDA 2599, ''Establishment License Application for the Manufacture of Blood and Blood Components;'' and Form FDA 2599a, ''Supplement to Establishment License Application for the Manufacture of Blood and Blood Components.'' As announced in the **Federal Register** of May 14, 1996 (61 FR 24313), CBER also is using interim Form FDA 3439, pending availability of the harmonized form for biotechnology products specified in § 601.2(c). Sixteen product license application forms are currently in use by CBER as follows: Form FDA 2600, ''Product License Application for the Manufacture of Source Plasma;'' Form FDA 2600b, ''Product License Application for Therapeutic Exchange Plasma;'' Form FDA 3066, ''Product License Application for Manufacture of Blood Grouping Reagents;'' Form FDA 3086, ''Product License Application for the Manufacture of Reagent Red Blood Cells;'' Form FDA 3096, ''Product License Application for the Manufacture of Anti-Human Globulin;'' Form FDA 3098, ''Product License Application for the Manufacture of Whole Blood and Blood Components;'' Form FDA 3098a, ''Product License Application for Red Blood Cells;'' Form FDA 3098b, ''Product License Application for Plasma;'' Form FDA 3098c, ''Product License Application for Platelets;'' Form FDA 3098d, ''Product License Application for Cryoprecipitated Antihemophilic Factor;'' Form FDA 3098e, ''The Manufacture of Products Prepared by Cytapheresis;'' Form FDA 3211, ''Application for License for the Manufacture of Viral and Rickettsial Vaccines;'' Form FDA 3212, ''Application for License for the Manufacture of Bacterial Vaccines and Antigens;'' Form FDA 3213, ''Application for License for the Manufacture of Allergenic Products;'' Form FDA 3214, ''Application for the Manufacture of a Human Plasma Derivative;'' and Form FDA 3314, ''Product License Application for the Manufacture of Human Immunodeficiency Virus for In-Vitro Diagnostic Use.''

CDER currently uses one application form, Form FDA 356h, ''Application to Market a New Drug for Human Use or an Antibiotic Drug for Human Use,'' dated October 1993. FDA intends eventually to replace all 20 application forms listed above with one harmonized application form for all biological products and drugs subject to premarket approval. FDA believes that a harmonized application format will allow companies to provide higher quality submissions, reduce preparation time, expedite review by FDA, and easily adapt to electronic submissions when that becomes possible and practical. FDA intends to phase in the use of the new Form FDA 356h as described in this notice.

This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives. One goal of these initiatives is to harmonize regulations administered by FDA in an effort to reduce unnecessary burdens for industry without diminishing public health protection.

Use of the new harmonized Form FDA 356h when fully implemented will allow a biologic product manufacturer to submit one biologic license application instead of two separate applications (product license application (PLA) and establishment license application (ELA)).

Applicants submitting an NDA, ANDA, or AADA may begin to use the new Form FDA 356h immediately. However, such applicants will be required to use the new Form FDA 356h beginning January 8, 1998. In the interim period the old Form FDA 356h, interim Form FDA 3439, and the new Form FDA 356h are all acceptable alternatives for NDA's, ANDA's, and AADA's.

For products currently submitted in the form of a biologics license application under section 351 (42 U.S.C. 262) of the PHS Act, including the biotechnology products specified in § 601.2(c), and autologous somatic cell therapy products, applicants may begin to use the new form immediately. The new Form FDA 356h will be required for products specified in § 601.2(c), and autologous somatic cell therapy products beginning January 8, 1998. Before this effective date, interim Form FDA 3439 is an acceptable alternative. Guidance documents entitled ''Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use'' (61 FR 56243, October 31, 1996); ''Guidance for the Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products'' (62 FR 1460, January 10, 1997); and ''Guidance for Industry for the Submission of Chemistry, Manufacturing and Controls Information for Synthetic Peptide Substances'' (available via the CDER home page at http://www.fda.gov/CDER and select the ''Regulatory Guidance'' section) are available to assist applicants in preparing the chemistry, manufacturing, and controls (CMC) and establishment description sections of the application.

Until further notice, if the biological product is not specified in § 601.2(c) or is not an autologous somatic cell therapy product, applicants should continue to use the forms listed in this notice currently in use by CBER. For these other biological products, including vaccines, blood and blood components, in vitro diagnostic test kits used to screen the blood supply, naturally derived protein products, allergenic products, and all other biological products, a PLA and an ELA should continue to be submitted. In future **Federal Register** notices, FDA will advise applicants for the products not yet using the new Form FDA 356h, when they may voluntarily begin, and when they will be required to use the new Form FDA 356h. FDA is in the process of preparing guidance documents on the content and format of the CMC and establishment description sections of the new Form FDA 356h for those biological products not yet using the new form. As these guidance documents are completed, FDA will begin accepting the new Form FDA 356h.

The harmonized Form FDA 356h solicits information from the applicant in the following areas: (1) General applicant information, (2) product description, (3) application information, (4) establishment information, and (5) cross references to other applications. In addition, the form solicits 19 items, including information regarding labeling, CMC, nonclinical and clinical information, patent information, establishment description information, plus certifications.

II. Requests for Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the new harmonized Form FDA 356h. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

FDA will consider any comments received in determining whether revisions to the Form FDA 356th are warranted.

III. Electronic Access

An electronic version of this form is also available via Internet using the World Wide Web (WWW). For access, connect to the FDA Form Distribution Page at http://aosweb.psc.dhhs.gov/forms/fdaforms.htm.

Dated: June 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–17717 Filed 7–7–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of January 10, 1997 (62 FR 1462). The document was amended to reflect the realignment of the Office of Health and Industry Programs, Center for Devices and Radiological Health, Office of Operations, FDA, under part H, chapter HF (FDA) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services. The agency inadvertently omitted a paragraph from the document. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: LTonya L. Barnes, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4807.

In FR Doc. 97–578, appearing on page 1462 in the **Federal Register** of Friday, January 10, 1997, the following correction is made:

1. On page 1462, in the second column, a new fourth paragraph is added to read ''Manages the Staff College to develop, coordinate, and provide continuing education and training for center employees.''

Dated: June 30, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–17718 Filed 7–7–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection Submitted to the Office of Management and Budget (OMB) for Extension Approval Under the Paperwork Reduction Act

ACTION: Notice.

SUMMARY: The proposal for the collection of information listed below has been submitted to OMB for extension approval under the provisions of the Paperwork Reduction Act. Copies of the proposed information collection