drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

Lachman Consultant Services, Inc., submitted a citizen petition dated December 5, 2002 (Docket No. 02P–0506/CP1), under 21 CFR 10.30 to FDA requesting that the agency determine whether hyaluronidase for injection was withdrawn from sale for reasons of safety or effectiveness. On January 8, 2003, Amphastar Pharmaceuticals, Inc., submitted a citizen petition (Docket No. 03P–0021/CP1) requesting the same action. On July 15, 2003, Merchant-Taylor International, Inc. (MTI), on behalf of Hyalozyme Therapeutics, Inc., filed a comment to both citizen petitions requesting that FDA determine that hyaluronidase for injection was withdrawn from sale for reasons of safety and effectiveness. Hyaluronidase for injection is the subject of approved NDA 6–343, formerly held by Wyeth Pharmaceuticals, Inc. (Wyeth), now held by Baxter Healthcare Corp. Hyaluronidase for injection is a protein enzyme and is a preparation of highly purified bovine testicular hyaluronidase used to increase the absorption and dispersion of other injected drugs. Wyeth ceased manufacture of hyaluronidase for injection in December 2001, and it was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book.

FDA has reviewed its records and the comment filed by MTI and, under § 314.161, has determined that hyaluronidase for injection was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list hyaluronidase for injection in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to hyaluronidase for injection may be approved by the agency; however, FDA recommends that in considering whether to file an ANDA for this drug product, future applicants be advised that such an application is likely to raise complex issues regarding the characterization of the active ingredient under section 505(j) of the act (see docket on conjugated estrogen drug products, Docket No. 98P–0311).

Dated: October 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–27880 Filed 11–5–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

List of Accredited Persons; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the list of persons who are accredited under certain circumstances to inspect eligible manufacturers of class II and class III devices in lieu of an FDA inspection. This list provides the identity of each accredited person and the particular activities for which the person is accredited. FDA is taking this action to implement provisions of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

ADDRESSES: This list is available on the Internet at *http://www.fda.gov/cdrh/ap-inspection/.* Submit a written request for copies of the List of Accredited Persons to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the list of accredited persons.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 124.

SUPPLEMENTARY INFORMATION:

I. Background

MDUFMA (Public Law 107–250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a paragraph ''g'' to section 704 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons or APs) to conduct inspections of eligible manufacturers of class II or class III devices. Participation in the program is voluntary. Manufacturers may continue to have FDA perform inspections or, if eligible, they may utilize an accredited person. The new law requires FDA, within 180 days from the date MDUFMA was signed into law, to publish in the **Federal Register**, criteria to accredit or deny accreditation to persons who request to perform these inspections (section 704(g)(2) of the act). FDA published the criteria it used to accredit persons for the purpose of conducting inspections of eligible manufacturers of class II and class III devices in the **Federal Register** of April 28, 2003 (68 FR 22400).

The new law also directed FDA to accredit up to 15 third parties to conduct inspections by no later than 1 year after MDUFMA was enacted and to publish on the FDA Internet site a list of persons who are accredited (21 U.S.C. 374(g) (4)). Under the new provision, FDA must update this list to ensure that the identity of each accredited person, and the particular activities for which the person is accredited, is known to the public. Under this new provision, FDA must also update the list no later than 1 month after the accreditation of a person, or the suspension or withdrawal of accreditation, or the modification of the particular activities for which the person is accredited.

FDA is currently developing guidance to help establishments determine whether they are qualified to participate in the third party inspection program. Because all accredited persons will have to complete training before conducting independent inspections under the new program, these APs will not be available to companies for several months. FDA plans to make the guidance available before the APs have completed the training. In the meantime, any company that is interested in participating in the third party inspection program may contact the contact person (see **FOR FURTHER INFORMATION CONTACT**) to get more information about eligibility.

II. Electronic Access

Persons interested in obtaining a copy of the list of accredited persons may also do so by using the Internet. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. The list of accredited persons is available at *http://www.fda.gov/cdrh/ap-inspection/*.

To receive the list of accredited persons by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1500) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Dated: October 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–27879 Filed 11–5–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2003M–0287, 2003M–0271, 2003M–0272, 2003M–0262, 2003M–0175, 2003M–0240, 2003M–0189, 2003M–0241, 2003M–0332, 2003M–0337, 2003M–0174, 2003M–0173, 2003M–0190, 2003M–0343, 2003M–0242, 2003M–0333, 2003M–0339, 2003M–0320, 2003M–0352, 2003M-0157]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** January 30, 1998 (63 FR 4571), FDA revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information to FDA's home page at *http://www.fda.gov* on the Internet. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from April 1, 2003, through June 30, 2003. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE APRIL 1, 2003, THROUGH JUNE 30, 2003

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P010052/2003M–0287	Diagnostic Products Corp.	Immulite/Immulite 2000 Anti-HBS	July 22, 2002
P010051/2003M–0271	Diagnostic Products Corp.	Immulite/Immulite 2000 Anti-HBC	July 24, 2002
P010053/2003M–0272	Diagnostic Products Corp.	Immulite/Immulite 2000 Anti-HBC IGM	July 26, 2002
P010050/2003M–0262	Diagnostic Products Corp.	Immulite/Immulite 2000 HBSAF and Immulite HBSAF Confirmatory Kit	July 26, 2002
P020014/2003M–0175	Conceptus, Inc.	Essure System	November 4, 2002
P990069/2003M–0240	EpMed Systems, Inc.	Alert System (Alert Catheter, Alert Interface Cable, and Alert Companion With Software Version 1.08)	November 27, 2002
P010055/2003M–0189	Prostalund Operations AB	Prostalund Coretherm System Microwave Thermotherapy for BPH	December 23, 2002
P020028/2003M–0241	Philips Medical System	Series 50 XMO (Model M1350C) Fetal/Maternal Monitor System With Integrated Fetal Oxygen Saturation Monitoring	January 3, 2003