in the spread of these pathogens. Pathogens that can cause diseases after an infected person handles food are the following:

Noroviruses
Hepatitis A virus
Salmonella Typhi*
Shigella species
Staphylococcus aureus
Streptococcus pyogenes

II. Pathogens Occasionally Transmitted by Food Contaminated by Infected Persons Who Handle Food, But Usually Transmitted by Contamination at the Source or in Food Processing or by Non-foodborne Routes

Other pathogens are occasionally transmitted by infected persons who handle food, but usually cause disease when food is intrinsically contaminated or cross-contaminated during processing or preparation. Bacterial pathogens in this category often require a period of temperature abuse to permit their multiplication to an infectious dose before they will cause disease in consumers. Preventing food contact by persons who have an acute diarrheal illness will decrease the risk of transmitting the following pathogens:

Campylobacter jejuni
Cryptosporidium parvum
Entamoeba histolytica
Enterohemorrhagic Escherichia coli
Enterotoxigenic Escherichia coli
Giardia lamblia
Nontyphoidal Salmonella
Taenia solium
Vibrio cholerae 01
Yersinia enterocolitica

References

1. World Health Organization. Health surveillance and management procedures for food-handling personnel: report of a WHO consultation. World Health Organization technical report series; 785. Geneva: World Health Organization, 1989.

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3. Bennett JV, Holmberg SD, Rogers MF, Solomon SL. Infectious and parasitic diseases. In: Amler RW, Dull HB, eds. Closing the gap: the burden of unnecessary illness. New York: Oxford University Press, 1987: 102–114.

4. Centers for Disease Control and Prevention. Locally acquired neurocysticercosis—North Carolina, Massachusetts, and South Carolina, 1989–1991. MMWR 1992; 41: 1–4.

5. Centers for Disease Control and Prevention. Foodborne Outbreak of Cryptosporidiosis-Spokane, Washington, 1997. MMWR 1998; 47:27.

* 1. Kauffmann-White scheme for designation of Salmonella serotypes

Dated: October 31, 2003.

Joseph R. Carter,

Deputy Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 03–27923 Filed 11–5–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0017]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Impact of Risk Management Programs on the Practice of Pharmacy

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Impact of Risk Management Programs on the Practice of Pharmacy ''has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 11, 2003, (68 FR 41384), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0516. The approval expires on October 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: October 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–27881 Filed 11–5–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2002P–0506 and 2003P–0021]

Determination That Hyaluronidase For Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that hyaluronidase for injection (Wydase) was not withdrawn from sale for reasons of safety or effectiveness. While this determination will allow FDA to approve abbreviated new drug applications (ANDAs) for hyaluronidase for injection, in considering whether to file an ANDA for this product, future applicants are advised that such an application raises complex issues regarding the characterization of the active ingredient.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations,

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]

BILLING CODE 4160–01–S

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/*.