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.

2. Frank JF, Barnhart HM. Food and dairy sanitation. In: Last JM, ed. Maxcy-Rosenau public health and preventive medicine, 12th edition. New York Appleton-Century-Crofts, 1986: 765–806.

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,