DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration
[Docket No. 00N–0356]

Agency Information Collection
Activities; Submission for OMB
Review; Comment Request; Survey of
Incidence of Gastroenterological
Parasitic Infections in the United
States as a Result of Consumption of
Raw Fish

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug
Administration (FDA) is announcing
that the proposed collection of
information listed below has been
submitted to the Office of Management
and Budget (OMB) for review and
clearance under the Paperwork

DATES: Submit written comments on
the collection of information by June 22,
2000.

ADDRESSES: Submit written comments
on the collection of information to the
Office of Information and Regulatory
Affairs, OMB, New Executive Office
Bldg., 725 17th St. NW., rm. 10235,
Washington, DC 20503. Attn: Wendy
Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT:
Peggy Schlosburg, Office of Information
Resources Management (HFA–250),
Food and Drug Administration, 5600
Fishers Lane, Rockville, MD 20857,
301–827–1223.

SUPPLEMENTARY INFORMATION:
In compliance with 44 U.S.C. 3507, FDA
has submitted the following proposed
collection of information to OMB for
review and clearance.

Survey of Incidence of
Gastroenterological Parasitic Infections
in the United States as a Result of
Consumption of Raw Fish

Under section 903(b)(2) of the Federal
Food, Drug, and Cosmetic Act (21 U.S.C.
393(b)(2)), FDA has the responsibility to
conduct research relating to foods and
to conduct educational and public
information programs relating to the
safety of the nation’s food supply. The
“Survey of Incidence of Gastroenterological
Parasitic Infections in the United States as a
Result of Consumption of Raw Fish” will provide
information on the actual frequency of
occurrence of fish-borne helminth
illnesses. Detailed information will be
obtained from the target population of
clinical gastroenterologists who are
likely to have encountered and treated
food-borne parasitic infections.

Any findings of significant levels of
infection will guide FDA in evaluating
its current policy that fish intended for
raw consumption should have been
previously frozen to eliminate the
hazard from live parasites. This
recommendation is adhered to by many
members of the seafood industry. To the
extent that parasite infection from raw
fish is demonstrated through this survey
to be a hazard reasonably likely to
cause illness, the agency would focus its
attention to such actions as increased
consumer education, which would
apply to raw fish from any source, and
to ensuring the implementation of
hazard analysis critical control points
controls for fish sold for raw
consumption.

FDA estimates the burden of
this collection of information as follows:

<table>
<thead>
<tr>
<th>No. of Respondents</th>
<th>Annual Frequency per Response</th>
<th>Total Annual Responses</th>
<th>Hours per Response</th>
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<td>1</td>
<td>500</td>
<td>.50</td>
<td>250</td>
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1There are no capital costs or operating and maintenance costs associated with this collection of information.
This is a one-time survey. The burden estimate is based on FDA’s experience with conducting similar surveys.

William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacological Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Psychopharmacological Drugs Advisory Committee

General Function of the Committee: To provide advice and recommendations to the agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on July 19, 2000, 8 a.m. to 5 p.m.
Location: Holiday Inn, Versailles Ballrooms I, II, and III, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Sandra L. Titus or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, Rm. 1093) Rockville, MD 20857, 301–827–7001, or e-mail Tituss@cdier.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area) code 12544. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will consider the safety and efficacy of new drug application (NDA) 20–825, Zeldox™ (ziprasidone hydrochloride capsules, Pfizer, Inc.), proposed for the management of psychotic disorders.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 17, 2000. Oral presentations from the public will be scheduled on July 19, 2000, between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 17, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Linda A. Suydam,
Senior Associate Commissioner.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU’s between FDA and others shall be published in the Federal Register, the agency is publishing notice of this MOU.

William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

The MOU is set forth in its entirety as follows:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Memorandum of Understanding Between the Food and Drug Administration, U.S. Department of Health and Human Services, and the Food Safety and Inspection Service, U.S. Department of Agriculture, Regarding the Listing or Approval of Food Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Food Safety and Inspection Service, U.S. Department of Agriculture (FSIS). The purpose of the agreement is to establish the working relationship to be followed by FDA and FSIS in responding to requests for the sanctioning of the use of food ingredients and sources of radiation subject to regulation by FDA and intended for use in the production of meat and meat food products.


BILLING CODE 4160–01–F