

*Purpose:* At this meeting the Work Group will continue to gather information and discuss issues related to the development of standards for electronic medical records. The Working Group will hear from panelists of data quality experts, code set developers and users, and standards users. The Work Group will also review progress on the Government's Computerized Patient Records initiative, develop agendas for future meetings, and discuss its future report to the Department of Health and Human Services.

*Notice:* In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey building by non-government employees. Thus, persons without a government identification card will need to have the guard call for an escort to the meeting.

*Contact Person for More Information:* Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from J. Michael Fitzmaurice, Ph.D., Agency for Health Care Policy and Research, 2101 East Jefferson Street, #602, Rockville, MD 20852, phone: 301-594-1483, x1052; or Marjorie S. Greenberg, Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 436-7050. Information also is available on the NCVHS home page of the HHS website: <http://aspe.os.dhhs.gov/ncvhs>, where an agenda for the meeting will be posted when available.

Dated: October 1, 1999.

**James Scanlon,**

*Director, Division of Data Policy, Office of the Assistant Secretary for Planning and Evaluation.*

[FR Doc. 99-26140 Filed 10-6-99; 8:45 am]

BILLING CODE 4151-04-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99N-1010]

#### Agency Information Collection Activities; Announcement of OMB Approval; Investigational New Drug (IND) Regulations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Investigational New Drug (IND) Regulations" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 6, 1999 (64 FR 24402), 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 0910-0014. The approval expires on September 30, 2002. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: September 30, 1999.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning and Legislation.*

[FR Doc. 99-26103 Filed 10-6-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98N-0222]

#### Agency Information Collection Activities; Announcement of OMB Approval; Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of November 20, 1998 (63 FR 64555), 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 0910-0390. The approval expires on September 30, 2002. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: September 30, 1999.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning and Legislation.*

[FR Doc. 99-26104 Filed 10-6-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Export of American Ginseng

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice.

**SUMMARY:** The Service seeks comments and input on the conservation status of American ginseng (*Panax quinquefolius*) and the impact of harvest and international trade on the species. This review of the status of the species and related trade will assist in determining any appropriate modification to export restrictions for wild American ginseng during the 2000 harvest season and beyond.

**DATES:** We will consider comments and information submitted by all interested parties by February 4, 2000.

**ADDRESSES:** You may submit any comments or information by mail to the Office of Scientific Authority, U.S. Fish and Wildlife Service, Mail Stop ARLSQ-750, Washington, D.C. 20240, or via fax (703-358-2276). You may also submit comments via E-mail to: [r9osa@fws.gov](mailto:r9osa@fws.gov). You may inspect any comments and information we receive, by appointment only, from 8:00 a.m. to 4:30 p.m., Monday through Friday, at the Office of Scientific Authority, 4401 N. Fairfax Dr., Room 750, Arlington, Virginia.

**FOR FURTHER INFORMATION CONTACT:** Dr. Javier Alvarez, Office of Scientific Authority, U.S. Fish and Wildlife Service, Mail Stop ARLSQ-750, Washington, D.C. 20240 (phone: 703-358-1708; fax: 703-358-2276; e-mail: [r9osa@fws.gov](mailto:r9osa@fws.gov)).

**SUPPLEMENTARY INFORMATION:**

#### Background

American ginseng (*Panax quinquefolius*) was listed in Appendix II of the Convention on International

Trade in Endangered Species of Wild Fauna and Flora (CITES) on February 22, 1977. The Department of the Interior is designated by the U.S. Endangered Species Act as both the CITES Management and Scientific Authority, and is therefore obligated to regulate the export of American ginseng, including whole plants, whole roots, and root parts. Those functions have been delegated to the Office of Management Authority and the Office of Scientific Authority of the U.S. Fish and Wildlife Service. Under the authority of the CITES treaty (Article IV), implemented by the U.S. Endangered Species Act, we can only allow the export of American ginseng from the United States if the Office of Scientific Authority advises the Office of Management Authority that such export will not be detrimental to the survival of the species, and if the Office of Management Authority is satisfied that the specimens to be exported were not obtained in contravention of any laws for their protection (that is, they were legally acquired). CITES Article IV also requires that the Scientific Authority monitor the exports of all Appendix II species, including American ginseng, and determine whether any such exports "should be limited in order to maintain that species throughout its range at a level consistent with its role in the ecosystems in which it occurs and well above the level at which that species might become eligible for inclusion in Appendix I \* \* \*

The Office of Scientific Authority uses a wide range of information to ensure that the species remains at healthy population levels throughout its range and to determine whether export of ginseng will not be detrimental to the survival of the species. That information includes but is not limited to the following: (1) Whether such export occurred in the past, and has appreciably reduced abundance or distribution of the species; (2) whether such export has or is expected to increase, remain constant, or decrease; and (3) whether the life-history parameters of the species indicate that the present and projected levels of export will reduce appreciably the numbers or distribution of the species. The information is available from State regulatory agencies, industry representatives and associations, non-governmental organizations, and academic researchers.

Under both the CITES treaty and the Endangered Species Act, the Office of Scientific Authority has the option of issuing the required scientific findings on a permit-by-permit basis, or programmatically on a State-by-State

basis. There are native U.S. species listed in Appendix II for which the Office of Scientific Authority issues its non-detriment findings to the Management Authority on a shipment-by-shipment basis, while there are others for which the Office of Scientific Authority issues findings on a State-by-State basis. Since the inclusion of American ginseng in CITES Appendix II in 1977, the Office of Scientific Authority has issued its findings on a State-by-State basis.

To determine whether or not to approve exports of American ginseng harvested in a State, the Office of Scientific Authority annually reviews publicly available data from many sources, including each State with a ginseng harvest program, on the general status of the species in each State. Based on information available (such as pounds of wild ginseng harvested; average roots/lb; average age of harvested plants estimated by counting bud scars or converting dry weight to age; and trends in abundance of wild ginseng populations as measured in field surveys), the Office of Scientific Authority makes a finding on the continued export of wild ginseng from a specific State. Information on ginseng harvest programs are reviewed and compared with information from previous harvest seasons by the Office of Scientific Authority and Office of Management Authority on June of each year. Afterwards, a finding on the export of ginseng to be harvested during the year in question is made by the Office of Scientific Authority early in the summer.

On August 2, 1999, the Office of Scientific Authority issued its finding on the export of American ginseng harvested during the 1999 season from States with ginseng harvest programs. Although the Office of Scientific Authority was able to make a positive finding, it was able to do so only for ginseng roots 5 years old or older, and not for all roots (as in previous years). We conditioned our non-detriment finding after reviewing the best scientific information currently available to the Office of Scientific Authority on the biology and status of American ginseng. Through communications with biologists from Great Smoky Mountains National Park and National Forests throughout the species' range (including those in Arkansas, Georgia, Illinois, Indiana, Kentucky, Michigan, North Carolina, Ohio, Pennsylvania, Virginia, West Virginia, and Wisconsin), the Office of Scientific Authority has become aware that ginseng plants are not only being over-harvested in some parts of the

country, but also that plants harvested are not afforded the opportunity to reach reproductive age and produce seeds. Independent ginseng researchers have contacted the Office of Scientific Authority concerning their surveys of ginseng populations in States that do not have wild ginseng harvest programs. They have found further evidence that young ginseng plants are being harvested and that ginseng populations may not be able to sustain harvest of such young plants.

Given that wild ginseng does not propagate asexually, it is critical that plants be allowed to reach reproductive age and produce seeds prior to their harvest so as to ensure replacement of the harvested plants and long-term survival of the species. Most ginseng plants start producing seeds when they attain 2 leaves (also known as prongs) at 3 to 4 years of age (R. C. Anderson, J. S. Fralish, J. E. Armstrong, and P. K. Benjamin. 1984. Biology of ginseng, *Panax quinquefolius*, in Illinois. Illinois Department of Conservation, Division of Forest Resources and Natural Heritage, Springfield, Illinois. 32 pages.) Ginseng plants add a third prong between 5 and 9 years of age, with the majority of them doing so when they are 7 years old.

Based on the above information and to ensure that ginseng plants harvested from the wild reach reproductive age and produce seeds for at least two seasons, the Office of Scientific Authority requested in its August 2, 1999 finding that the Office of Management Authority, which is responsible for issuing CITES permits, condition permits for the export of ginseng roots harvested from the wild in the 1999 season so as to allow only export of roots that are 5 years of age or older. Without the inclusion of an age-based condition in each CITES export permit for wild American ginseng, we would not have found that the harvest of ginseng from the wild during the 1999 season is not detrimental to the survival of the species.

Most States with wild ginseng harvest programs (including Alabama, Arkansas, Georgia, Indiana, Iowa, Maryland, Minnesota, New York, Ohio, Pennsylvania, Tennessee, Vermont, West Virginia, and Wisconsin) already have regulations in place that prohibit the harvest of ginseng plants with less than three prongs (compound leaves); that is, harvested plants must be at least 5 years old. Therefore, the age-based restriction of export of wild ginseng roots does not constitute any new restriction on the harvest of wild ginseng roots in these States. We are simply assisting the States in the enforcement of their own regulations by

discouraging individuals from digging plants that have not yet reproduced, as well as discouraging dealers from purchasing roots of young plants. Likewise, as of August 30, 1999, the U.S. Forest Service—Eastern Region has also directed that permits for the collection of wild ginseng on National Forest lands (including Shawnee National Forest, Illinois; Hoosier National Forest, Indiana; Huron and Manistee National Forests, Michigan; Chippewa and Superior National Forests, Minnesota; Mark Twain National Forest, Missouri; Wayne National Forest, Ohio; Alleghany National Forest, Pennsylvania; Green Mountain National Forest, Vermont; Monongahela National Forest, West Virginia; Chequamegon-Nicolet National Forest, Wisconsin) be restricted to plants at least 5 years of age. Our ultimate objective is to prevent the extirpation from the wild of this valuable natural resource and the resultant negative economic impact this would have on citizens who depend on this plant as a source of income.

The issuance of a “non-detriment” finding by the Scientific Authority is required by both the Endangered Species Act and the CITES treaty as one of the prerequisites that must be met before any export permit can be issued for an Appendix-II species. As such, the non-detriment finding is one of several administrative determinations that comprise the decision-making process for the issuance of CITES permits. Prior to 1994, we issued multi-year findings on exports of American ginseng through a Notice in the **Federal Register** as an informational matter. For the past several years, we issued our findings on an annual administrative basis. New biological information available to us precludes the issuance of a multi-year non-detriment finding. The Service consulted with the ginseng program coordinators from all States where harvest of wild ginseng is allowed, prior to the Office of Scientific Authority issuing its 1999 finding.

The responsibility for inspection of all plant import and exports, including shipments of ginseng, rests with the U.S. Department of Agriculture Animal and Plant Health Inspection Service (APHIS). Policies on the inspection and clearance of plant shipments, including ginseng, are made by APHIS. We work closely with APHIS, and continue to work closely in the enforcement and implementation of the new permit condition.

#### Public Comments Solicited

In anticipation of the ginseng harvest season for 2000 and beyond, we are

seeking information from the public, other concerned governmental agencies, the scientific community, the trade industry, or any other interested party on the status of ginseng populations in the wild. We particularly seek biological and trade information concerning the impact of ginseng harvest and international trade on wild populations of the species, the current conservation status of the species throughout its range, or other relevant data concerning any threat to the species. Such information may lead us to modify current restrictions on the export of wild American ginseng during the 2000 harvest season, and beyond.

**Author:** The primary author of this notice is Dr. Javier Alvarez, Office of Scientific Authority, U.S. Fish and Wildlife Service, Mail Stop ARLSQ-750, Washington, D.C. 20240.

**Dated:** September 30, 1999.

**Jamie Rappaport Clark,**

*Director.*

[FR Doc. 99-26205 Filed 10-6-99; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Aquatic Nuisance Species Task Force Great Lakes Panel Meeting and Ruffe Control Committee Meeting

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of meetings.

**SUMMARY:** This notice announces meetings of the Aquatic Nuisance Species (ANS) Task Force Great Lakes Panel Committee and the Ruffe Control Committee. The meeting topics are identified in the **SUPPLEMENTARY INFORMATION**.

**DATES:** The Great Lakes Panel will meet 1 p.m. to 5 p.m. on Tuesday, October 19, 1999, and 8 a.m. to 12 noon on Wednesday, October 20, 1999. The Ruffe Control Committee will meet from 1 p.m. to 5 p.m. on Thursday, October 28, 1999, and 8 a.m. to 12 noon on Friday, October 29, 1999.

**ADDRESSES:** The Great Lakes Panel meeting will be held at Metcalfe Federal Office Building, 77 W. Jackson Boulevard, Chicago, Illinois and the Ruffe Control Committee meeting will be held at the Best Western Inn, 6285 Saginaw Road, Bay City, Michigan.

**FOR FURTHER INFORMATION CONTACT:** Sharon Gross, Executive Secretary, Aquatic Nuisance Species Task Force at 703-358-2308 or by e-mail at: sharon\_gross@fws.gov.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. I), this notice announces meetings of the Aquatic Nuisance Species Task Force Great Lakes Panel Committee and the Ruffe Control Committee. The Task Force was established by the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990.

The Great Lakes Panel, comprised of representatives from Federal, State, and local agencies and from private environmental and commercial interests, provides the following:

(a) Identify priorities for the Great Lakes Region with respect to aquatic nuisance species;

(b) Make recommendations to the Task Force regarding programs to carry out zebra mussel programs;

(c) Assist the Task Force in coordinating Federal aquatic nuisance species program activities in the Great Lakes region;

(d) Coordinate, where possible, aquatic nuisance species program activities in the Great Lakes region that are not conducted pursuant to the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 (as amended, 1996);

(e) Provide advice to public and private individuals and entities concerning methods of controlling aquatic nuisance species; and

(f) Submit an annual report describing activities within the Great Lakes region related to aquatic nuisance species prevention, research, and control.

The focus of this meeting will be to: review Panel activities for the past year, hear updates of ongoing activities, and review the Great Lakes Action Plan.

Topics to be covered at the Ruffe Control Committee meeting will include: the status of existing ruffe populations, a detailed review of each of the eight components of the ruffe control plan, an evaluation of the bait harvest prohibitions currently in place on Lake Superior, and other topics.

Minutes of the meeting will be maintained by the Executive Secretary, Aquatic Nuisance Species Task Force, Suite 851, 4401 North Fairfax Drive, Arlington, Virginia 22203-1622, and will be available for public inspection during regular business hours, Monday through Friday.

**Dated:** October 1, 1999.

**Hannibal Bolton,**

*Acting Co-Chair, Aquatic Nuisance Species Task Force, Acting Assistant Director—Fisheries.*

[FR Doc. 99-26125 Filed 10-6-99; 8:45 am]

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