comments regarding this document. It is only necessary to submit one set of comments. Identify comments with the docket number found in the brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**XX. References**

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Schiano, T.D., ''Clinical Management of Hepatic Encephalopathy,'' vol. 30, pp. 10S–15S, *Pharmacotherapy,* 2010.
2. Blozan, C.F. and S.A. Tucker, ''Premarket Notifications: The First 24,000,'' pp. 59–69, *Medical Device & Diagnostic Industry,* 1986.
3. Geiger, D.R., ''FY 2003 and FY 2004 Unit Costs for the Process of Medical Device Review,'' (*http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109216.pdf*), September 2005.

**List of Subjects in 21 CFR Part 876**

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 876 be amended as follows:

## PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 876.5870 is amended by revising paragraphs (b) and (c) to read as follows:

**§ 876.5870 Sorbent hemoperfusion system.**

* * * * *

(b) *Classification.* (1) Class II (special controls) when the device is intended for the treatment of poisoning and drug overdose. The special controls for this device are:

(i) The device should be demonstrated to be biocompatible;

(ii) Performance data to demonstrate the mechanical integrity of the device (e.g., tensile, flexural, and structural strength), including testing for the possibility of leaks, ruptures, release of particles, and/or disconnections;

(iii) Performance data to demonstrate device sterility and shelf life;

(iv) Bench performance data to demonstrate device functionality in terms of substances, toxins, and drugs removed by the device, and the extent that these are removed when the device is used according to its labeling;

(v) Summary of clinical experience with the device that discusses and analyzes device safety and performance, including a list of adverse events observed during the testing;

(vi) Labeling controls, including appropriate warnings, precautions, cautions, and contraindications statements to alert and inform users of proper device use and potential clinical adverse effects, including blood loss, platelet loss, leukopenia, hemolysis, hypotension, clotting, metabolic disturbances, and loss of vital nutrients and substances; Labeling recommendations must be consistent with the performance data obtained for the device, and must include a list of the drugs the device has been demonstrated to remove, and the extent for removal/depletion; and

(vii) For those devices that incorporate electrical components, appropriate analysis and testing to validate electrical safety and electromagnetic compatibility.

(2) Class III (premarket approval) when the device is intended for the treatment of hepatic coma and metabolic disturbances.

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with FDA on or before [date 90 days after date of publication of the final rule in the **Federal Register**], for any sorbent hemoperfusion system indicated for treatment of hepatic coma or metabolic disturbances that was in commercial distribution before May 28, 1976, or that has, on or before [date 90 days after date of publication of the final rule in the **Federal Register**], been found to be substantially equivalent to any sorbent hemoperfusion device indicated for treatment of hepatic coma or metabolic disturbances that was in commercial distribution before May 28, 1976. Any other sorbent hemoperfusion system device indicated for treatment of hepatic coma or metabolic disturbances shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: February 14, 2012.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2012–3810 Filed 2–16–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF DEFENSE

### Defense Acquisition Regulations System

### 48 CFR Part 242

**RIN 0750–AH52**

### Defense Federal Acquisition Regulation Supplement; DoD Voucher Processing (DFARS Case 2011–D054)

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Proposed rule; clarification.

**SUMMARY:** DoD is clarifying the rule published on January 19, 2012, proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to update DoD's voucher processing procedures and better accommodate the use of Wide Area WorkFlow to process vouchers.

**DATES:** *Comments* on the proposed rule published January 19, 2012, at 77 FR 2682, continue to be accepted until March 19, 2012.

**FOR FURTHER INFORMATION CONTACT:** Mr. Mark Gomersall, Defense Acquisition Regulations System, OUSD (AT&L) DPAP (DARS), Room 3B855, 3060 Defense Pentagon, Washington, DC 20301–3060. Telephone 703–602–0302; facsimile 703–602–0350.

**SUPPLEMENTARY INFORMATION:** DoD is clarifying the proposed rule published on January 19, 2012 (77 FR 2682), which proposes to revise requirements for approving interim vouchers. Interim vouchers that are selected using risk-based sampling methodologies will be reviewed and approved by the contract auditors for provisional payment and sent to the disbursing office after the pre-payment review. Interim vouchers not selected for a pre-payment review will be considered acceptable for payment and will be sent directly to the disbursing office. All interim vouchers are subject to an audit of actual costs incurred after payment. The sampling process will be accomplished largely within the Wide Area WorkFlow system.

The rule proposes to revise the requirements for approving interim vouchers by replacing the direct submission process currently referenced

at DFARS 242.803(b)(i)(C) with a risk-based sampling process. The proposed risk-based sampling process is a more effective and efficient approach. It allows for the evaluation of selected interim vouchers on a pre-payment basis in lieu of the current direct submission authorization, which does not allow for the pre-payment evaluation of higher risk interim vouchers. It is anticipated that the revised process will provide a more comprehensive sample of all vouchers and an enhanced oversight of higher risk vouchers, while allowing a more efficient processing of the vouchers not selected for pre-payment review.

**List of Subjects in 48 CFR Part 242**

Government procurement.

**Ynette R. Shelkin,**

*Editor, Defense Acquisition Regulations System.*

[FR Doc. 2012–3659 Filed 2–16–12; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## 50 CFR Part 17

**[Docket No. FWS–R8–ES–2012–0001; 4500030113]**

## Endangered and Threatened Wildlife and Plants; 90-Day Finding on a Petition To List the Thermophilic Ostracod as Endangered or Threatened

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

**ACTION:** Notice of 90-day petition finding.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, announce a 90-day finding on a petition to list the thermophilic ostracod (*Potamocypris hunteri*) as endangered or threatened under the Endangered Species Act of 1973, as amended (Act). Based on our review, we find that the petition does not present substantial information indicating that listing the thermophilic ostracod may be warranted. Therefore, we are not initiating a status review in response to this petition. We ask the public to submit to us any new information that becomes available concerning the status of, or threats to, the thermophilic ostracod or its habitat at any time.

**DATES:** The finding announced in this document was made on February 17, 2012.

**ADDRESSES:** This finding is available on the Internet at *http://www.regulations.gov* at Docket Number FWS–R8–ES–2012–0001. Supporting documentation we used in preparing this finding is available for public inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Klamath Falls Fish and Wildlife Office, 1936 California Avenue, Klamath Falls, CA 97601. Please submit any new information, materials, comments, or questions concerning this finding to the above street address.

**FOR FURTHER INFORMATION CONTACT:** Laurie Sada, Field Supervisor, Klamath Falls Fish and Wildlife Office (see **ADDRESSES**), by telephone at 541–885–2507, or by facsimile to 541–885–7837. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800–877–8339.

**SUPPLEMENTARY INFORMATION:**

### Background

Section 4(b)(3)(A) of the Act (16 U.S.C. 1531 *et seq.*) requires that we make a finding on whether a petition to list, delist, or reclassify a species presents substantial scientific or commercial information indicating that the petitioned action may be warranted. We are to base this finding on information provided in the petition, supporting information submitted with the petition, and information otherwise available in our files. To the maximum extent practicable, we are to make this finding within 90 days of our receipt of the petition, and publish our notice of the finding promptly in the **Federal Register**.

Our standard for substantial scientific or commercial information within the Code of Federal Regulations (CFR) with regard to a 90-day petition finding is ''that amount of information that would lead a reasonable person to believe that the measure proposed in the petition may be warranted'' (50 CFR 424.14(b)). If we find that substantial scientific or commercial information was presented, we are required to promptly conduct a species status review, which we subsequently summarize in our 12-month finding.

*Petition History*

On March 8, 2011, we received a petition dated March 4, 2011, from Chris Zinda (Friends of Hunter's Hot Springs) and Drs. Brendan Bohannan and Richard Castenholz (University of Oregon) requesting that the thermophilic ostracod (*Potamocypris hunteri*) be listed as endangered or threatened under the Act. The petition clearly identified itself as such and included the requisite identification information for the petitioner, as required by 50 CFR 424.14(a). In a May 4, 2011, letter to the petitioner, we responded that we had reviewed the information presented in the petition and determined that issuing an emergency regulation temporarily listing the species under section 4(b)(7) of the Act was not warranted. We also stated that we were required to complete a significant number of listing and critical habitat actions in Fiscal Year 2011 pursuant to court orders, judicially approved settlement agreements, and other statutory deadlines, but that we had secured funding for Fiscal Year 2012 and anticipated publishing a finding in the **Federal Register** in 2012. This finding addresses the petition.

*Evaluation of Listable Entity*

Section 3(16) of the Act defines the term ''species'' to include ''any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature.'' Entities that meet the Act's definition of a ''species'' can be considered for listing under the Act and are, therefore, referred to as ''listable entities.'' Listable entities can then be listed if they are determined to meet the definition of an endangered species or a threatened species. Prior to making a determination of whether the petition presents substantial information to indicate whether listing may be warranted, we must address the question of whether the petition presents substantial information to indicate whether the petitioned thermophilic ostracod may be a listable entity. We may consider the petitioned ostracod to be a listable entity if information submitted with the petition or in our files indicates that treatment of this ostracod as a listable entity may be warranted. Based on the information presented in the petition and information in our files, there is a considerable amount of uncertainty regarding the taxonomy of this entity. The following paragraphs present our evaluation of whether *Potamocypris hunteri* may be a listable entity.

Wickstrom and Castenholz (1973, p. 1063) reported finding what they considered to be a new undescribed species of *Potamocypris* at Hunter's Hot Springs (Hunter's) in southeastern Oregon. The Latin name *Potamocypris hunteri* was coined in a footnote in 1973, but not accompanied by a formal description (Wickstrom and Castenholz 1973, p. 1064). Wickstrom and