GUIDANCE DOCUMENTS ISSUED BY ORA—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| | | | Mailing Address | Internet Address |
| Draft Guidance—21 CFR Part 11; Electronic Records; Electronic Signatures Validation | August 2001 | Do. | Do. | |
| Draft Guidance—21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms | August 2001 | Do. | Do. | |
| Draft Guidance—21 CFR Part 11; Electronic Records; Electronic Signatures, Time Stamps | February 2002 | Do. | Do. | |
| Draft Guidance—21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records | July 2002 | Do. | Do. | |
| Compliance Policy Guide—Section 300.700: Direct Reference Authority for Class III Medical Devices Without a Premarket Notification (510(k)) or an Approved Premarket Approval Application (PMA) (CPG 7124.30) | February 26, 1991 | Do. | Do. | |
| Compliance Policy Guide—Section 405.100: Prescriptions Prepared From Certified Antibiotics (CPG 7122.01) | October 1, 1980 | Do. | Do. | |
| Compliance Policy Guide—Section 405.200: Export of Uncertified Antibiotics (CPG 7122.02) | October 1, 1980 | Do. | Do. | |
| Compliance Policy Guide—Section 405.210: Returned Antibiotics Exported Under 801(d) of the Act (CPG 7122.03) | July 1, 1981 | Do. | Do. | |
| Draft Compliance Policy Guide—Distributor Medical Device Reporting | August 28, 1997 | Do. | Do. | |

Dated: December 22, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05–155 Filed 1–4–05; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004N–0479]**

### Draft Risk Assessment of Streptogramin Resistance in Enterococcus faecium Attributable to the Use of Streptogramins in Animals; Extension of Comment Period

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

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to February 23, 2005, the comment period for the notice that appeared in the **Federal Register** of November 24, 2004 (69 FR 68384). In the notice, FDA requested comments on a draft risk assessment of the potential impact that food-animal use of streptogramin antimicrobials has on the resistance to chemically similar streptogramins used to treat human enterococcal infections. The agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

**DATES:** Submit written and electronic comments by February 23, 2005.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

**FOR FURTHER INFORMATION CONTACT:** Barry Hooberman, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–8557, e-mail: *bhooberm@cvm.fda.gov*.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

In the **Federal Register** of November 24, 2004 (69 FR 68384), FDA published a notice with a 60-day comment period to request comments on a draft risk assessment of the potential impact that food-animal use of streptogramin antimicrobials has on the resistance to chemically similar streptogramins used to treat human enterococcal infections. The veterinary drug of interest in this risk assessment is the streptogramin, virginiamycin, a drug approved for use in chicken, turkey, swine, and cattle feed. FDA will consider information received during the comment period in its preparation of a final risk assessment.

The agency has received a request for a 60-day extension of the comment period for the notice. This request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the notice.

FDA has considered the request and is extending the comment period for the notice for an additional 30 days, until February 23, 2005. The agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying the preparation of the final risk assessment.

**II. Request for Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in 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.

Dated: December 28, 2004.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 05–111 Filed 1–4–05; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the 41st meeting of the Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) National Advisory Council will be held in January 2005.

A portion of the meeting will be open and include discussion of the Center's policy issues, current administrative, legislative, and program developments. The meeting will also include the review, discussion, and evaluation of individual grant applications. Therefore a portion of the meeting will be closed to the public as determined by the SAMHSA Administrator, in accordance with Title 5 U.S.C. 552b(c) and (6) and 5 U.S.C. App. 2, § 10(d).

SAMHSA/CSAT welcomes the attendance of the public at its advisory council meetings, and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please inform the contact person by January 19.

Substantive program information, a summary of the meeting, transcript of the open session, and a roster of Council members may be obtained by accessing the SAMHSA Advisory Committee Web site (*http://www.samhsa.gov*), or by communicating with the contact whose name and telephone number are listed below.

*Committee Name:* SAMHSA's Center for Substance Abuse Treatment National Advisory Council.

*Meeting Dates:* January 26–9 a.m.–4 p.m. January 27–9 a.m.–1 p.m.

*Place:* 1 Choke Cherry Road, Sugar Loaf Room, Rockville, Maryland 20857.

*Type: Open:* January 26–9 a.m.–4 p.m.; *Closed:* January 27–9 a.m.–10:15 a.m.; *Open:* January 27–10:30 a.m.–1 p.m.

*Contact:* Cynthia Graham, Executive Secretary, SAMHSA/CSAT National Advisory Council, 1 Choke Cherry Road, Room 5–1036, Rockville, MD 20857, telephone: (240) 276–1692, FAX: (240) 276–1690, e-mail: *Cynthia.graham@samhsa.hhs.gov.*

Dated: December 29, 2004.

*Toian Vaughn, Committee Management Officer, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 05–188 Filed 1–4–05; 8:45 am]

**BILLING CODE 4162–20–P**

## DEPARTMENT OF HOMELAND SECURITY

### Transportation Security Administration

### Reports, Forms, and Record Keeping Requirements: Agency Information Collection Activity Under OMB Review; Flight Crew Self-Defense Training—Registration and Evaluation

**AGENCY:** Transportation Security Administration (TSA), DHS.

**ACTION:** Notice of emergency clearance request.

**SUMMARY:** The U.S. Department of Homeland Security, Transportation Security Administration, has submitted a request for emergency processing of a new public information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. 35). This notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to OMB for review and comment. The ICR describes the nature of the information collection and its expected burden.

**DATES:** Send your comments by February 4, 2005. A comment to OMB is most effective if OMB receives it within 30 days of publication.

**ADDRESSES:** Comments may be faxed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: DHS–TSA Desk Officer, at (202) 395–5806.

**FOR FURTHER INFORMATION CONTACT:** Lisa Dean, Privacy Officer, Office of Transportation Security Policy, TSA–9, Transportation Security Administration, 601 South 12th Street, Arlington, VA 22202–4220; telephone (571) 227–3947; facsimile (571) 227–2555.

**SUPPLEMENTARY INFORMATION:**

**Transportation Security Administration (TSA)**

*Title:* Flight Crew Self-Defense Training—Registration and Evaluation.

*Type of Request:* Emergency processing request of new collection.

*OMB Control Number:* Not yet assigned.

*Form(s):* ''Level 1 End-of-Course Evaluation''; ''Community College Sign-In Sheet.''

*Affected Public:* Flight and cabin crew on commercial passenger and cargo flights.

*Abstract:* Section 603 of Vision 100—Century of Aviation Reauthorization Act (Pub. L. 108–176) requires TSA to develop and provide a voluntary advanced self-defense training program for flight and cabin crew members of air carriers providing scheduled passenger air transportation. This collection would allow TSA to collect identifying information from volunteer flight and cabin crew members who register for self-defense classes, and would permit TSA to solicit voluntary feedback on the quality of the training. Due to an impending statutory deadline, TSA is seeking an emergency three-month authorization, until April 2005, to collect this information.

Identifying information would be gathered from trainees who have registered for a self-defense program to confirm that they are eligible for that program (i.e., that they are an active flight or cabin crew member for a commercial or cargo air carrier), and to confirm their attendance at the self-defense classes. The information that would be collected consists of the trainee's identifying information (such as the trainee's name and employee number), the name of their employer, and contact information. TSA will use a sign-in sheet to collect this information at the beginning of the self-defense course.

After training is completed, TSA would solicit written feedback from trainees by using a standard TSA training evaluation form. Completion of this form would be voluntary and anonymous.