early phase clinical studies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 201.57 have been approved under OMB control number 0910–0572.

III. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances*, or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances,* or *http://www.regulations.gov*.

Dated: February 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–3679 Filed 2–17–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0528]

Unapproved Animal Drugs; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to April 19, 2011, the comment period for the notice that appeared in the **Federal Register** of December 20, 2010 (75 FR 79383). In the notice FDA requested comments on strategies to address the prevalence of animal drug products marketed in the United States without approval or other legal marketing status. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: Submit electronic or written comments by April 19, 2011.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2010–N–0528 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2010–N–0528. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tracey H. Forfa, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9000, e-mail: *Tracey.Forfa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 20, 2010 (75 FR 79383), FDA published a notice with a 60-day comment period to request comments from stakeholders on strategies to address the prevalence of animal drug products marketed in the United States without approval or other legal marketing status. The notice expressed FDA's interest in receiving comments on strategies that utilize FDA's existing regulatory framework for addressing this issue as well as on novel strategies not currently employed by the Agency.

The Agency has received requests for a 60-day extension of the comment period. The requests conveyed concern that the current 60-day comment period does not allow respondents sufficient time to address fully the many important issues FDA raised in the notice.

FDA has considered the requests and is extending the comment period for the notice for 60 days, until April 19, 2011. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying the Agency's consideration of these important issues.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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: February 15, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–3712 Filed 2–17–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Correction of Burden Table.

SUMMARY: The Health Resources and Services Administration published an Agency Information Collection document in the **Federal Register** of

January 31, 2011 (FR Doc. 2011–1997), on page 5389, regarding the Data System for Organ Procurement and Transplantation Network (42 CFR Part 121, OMB No. 0915–0184): Extension. The Burden Table is incorrect.

Correction

In the **Federal Register** issue of January 31, 2011 (FR Doc. 2011–1997), on page 5389, correct the Burden Table as follows:

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Section and activity	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours
121.3(b)(2) OPTN membership and application requirements	40	3	120	15	1,800
121.3 Application for Non-Institutional Members	20	1	20	10	200
121.3(b)(4) Appeal for OPTN membership	2	1	2	3	6
121.6(c) (Reporting) Submitting criteria for organ acceptance	900	1	900	0.5	450
121.6(c) (Disclosure) Sending criteria to OPOs	900	1	900	0.5	450
121.7(b)(4) Reasons for Refusal	900	38	34,200	0.5	17,100
121.7(f) Transplant to prevent organ wastage	260	1.5	390	0.5	195
121.9(b) Designated Transplant Program Requirements	10	1	10	5.0	50
121.3 Personnel Change Application	324	1	324	10	3,240
121.9(d) Appeal for designation	2	1	2	6	12
Total	954		36,868		23,503

Dated: February 14, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011–3755 Filed 2–17–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Poison Control Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Noncompetitive Replacement Awards to the Research Foundation of SUNY and the New York City Health & Hospitals Corporation.

SUMMARY: HRSA will transfer funds and duties from Kaleida Health and University of Rochester to the Research Foundation of SUNY d.b.a. the Upstate New York Poison Control Center. HRSA will also transfer funds and duties from Winthrop University to the New York City Health & Hospitals Corporation d.b.a. the New York City Poison Control Center. These transfers are necessary in order to maintain poison control services and education efforts throughout the State of New York.

SUPPLEMENTARY INFORMATION:

Former Grantee of Record: Kaleida Health, University of Rochester; and Winthrop University are the three former grantees.

Original Period of Grant Support is from: September 1, 2009 to August 31, 2014.

Replacement awardees: The Research Foundation of SUNY and the New York City Health & Hospitals Corporation are the replacement awardees.

Period of Replacement Awards: The period of support for the replacement awards is January 1, 2011, to August 31, 2011.

Amount of Replacement Awards is as follows:

➢ Kaleida Health d.b.a. the Western New York Poison Center (H4BHS15474) will transfer $78,720 to the Research Foundation of SUNY d.b.a. the Upstate New York Poison Center (H4BHS15475);

➢ University of Rochester d.b.a. the Ruth A. Lawrence Poison and Drug Information Center (H4BHS15476) will transfer approximately $78,820 to the Research Foundation of SUNY d.b.a. the Upstate New York Poison Center (H4BHS15475); and

➢ Winthrop University d.b.a. the Long Island Regional Poison and Drug Information Center (H4BHS15478) will transfer $230,397 to the New York City Health & Hospitals Corporation d.b.a. the New York City Poison Control Center (H4BHS15477).

Authority: Section 1273 of the PHS (42 U.S.C. 300d—73), as amended by Poison Center Support Enhancement and Awareness Act of 2008.

CFDA Number: 93.253.

Justification for the Exception to Competition

The poison centers operated by the Research Foundation of SUNY and the New York City Health & Hospitals Corporation currently provide poison center services to the citizens of New York, 24 hours a day, 7 days a week. These services include telephone treatment advice and consultation about toxic exposures for both the public and health care professionals and toxico and public health surveillance. Educators at the centers provide public education about poison prevention and clinical toxicology training for many different healthcare professionals. The centers also offer programs to help clinicians better manage poisoning and overdose cases that end up in a healthcare facility.

These centers have the capacity to provide poison control service to the areas formerly served by Kaleida Health, University of Rochester, and Winthrop University, ensuring access to critical poison emergency treatment and poison