

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹—Continued

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours) ²	Total hours
211.132(c)	1,698	20	33,960	30/60	16,980
211.132(d)	1,698	.2	340	30/60	170
211.137	4,184	5	20,920	30/60	10,460
211.160(a)	4,184	2	8,368	1	8,368
211.165(e)	4,184	1	4,184	1	4,184
211.166(c)	4,184	2	8,368	30/60	4,184
211.173	1,077	1	1,077	15/60	269
211.180(e)	4,184	.2	837	15/60	209
211.180(f)	4,184	.2	837	1	837
211.182	4,184	2	8,368	15/60	2,092
211.184	4,184	3	12,552	30/60	6,276
211.186	4,184	10	41,840	2	83,680
211.188	4,184	25	104,600	2	209,200
211.192	4,184	2	8,368	1	8,368
211.194	4,184	25	104,600	30/60	52,300
211.196	4,184	25	104,600	15/60	26,150
211.198	4,184	5	20,920	1	20,920
211.204	4,184	10	41,840	30/60	20,920
Total					848,625

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format “[number of minutes per response] /60.”

Dated: May 24, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–13441 Filed 5–27–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0010]

Cooperative Arrangement Between the United States Food and Drug Administration and the Inter-American Institute for Cooperation in Agriculture

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a cooperative arrangement between FDA and the Inter-American Institute for Cooperation in Agriculture. The purpose of the arrangement is to provide a framework between the two Agencies to facilitate the exchange of information and the development of projects of mutual interest.

DATES: The arrangement became effective on April 15, 2011, for a duration of 5 years.

FOR FURTHER INFORMATION CONTACT: Moises O’Neill, Office of International Programs, Food and Drug Administration, 3440 San Jose Pl., Washington, DC 20521–3440, Tel. 506–2519–2220.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(a) and (c), which states that all written arrangements and understandings signed by FDA and other departments, Agencies, and organizations shall be published in the **Federal Register**, except those arrangements and memoranda of understanding between FDA and State or local government Agencies that are cooperative work-sharing arrangements, the Agency is publishing notice of this cooperative arrangement.

Dated: May 18, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

**Cooperative Arrangement
Between
The United States Food and Drug Administration
And
The Inter-American Institute for Cooperation on Agriculture**

I. Purpose

This Arrangement provides a framework between the United States (U.S.) Food and Drug Administration (FDA) and the Inter-American Institute for Cooperation on Agriculture (IICA) (hereafter referred to as the Participants) to facilitate the exchange of information and the development of projects of mutual interest.

Nothing in this Arrangement is intended to affect existing arrangements between the Participants.

II. Scope

FDA and IICA share a common interest in developing productive, safe, high quality food and agricultural systems consistent with public health principles; and in sharing expertise and technology in support of improved public health outcomes in the Americas. The technical and human resources of FDA and IICA, when brought together on projects of mutual interest related to food safety, have the potential to benefit IICA member states and their populations, including U.S. consumers. Activities of mutual interest may be developed in any area consistent with the parties' missions and strategic plans, including, but not limited to good agricultural practices, aquaculture, as well as food safety outreach, education, research, and technical assistance/capacity building.

III. Types of Cooperative Activities

Cooperative activities may include, but are not limited to, the following.

- Studies, research, scientific exchanges, technology transfer/innovation and other types of scientific and technological cooperation.
- Short-term specialized analytical and advisory projects such as the provision of technical services in connection with a specific project or program by means of a technical mission or individual expert(s).
- Technical and/or administrative support for the preparation and execution of projects.
- Publication of documents.
- Training, either in-service or through courses, seminars, study trips, and/or program work with academic institutions.
- Exchange of information, statistical data and methodologies.
- Personnel exchanges.

- Reciprocal invitations to meetings on technical or policy matters of mutual interest.
- Technical cooperation on public health and trade-related matters related to sanitary and phyto-sanitary (SPS) measures.
- Organization and sponsoring of conferences or workshops on subjects of common interest.

IV. Operating Procedures

The performance of specific activities may be subject to additional documentation as decided by the Participants.

V. Contacts

For purposes of this general arrangement, the representatives of the parties shall be:

For FDA:

Associate Commissioner for International Programs
Office of International Programs
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
United States of America
Tel. +1.301.796.4600
Facsimile: +1.301.595.7937

For IICA

Director
Technical Cooperation Directorate
Inter-American Institute for Cooperation on Agriculture
P.O. Box 55-2200 Coronado
San Jose, Vazquez de Coronado, San Isidro 11101
Costa Rica
Tel: +506.2216.0222
Facsimile: +506.2216.0233

VI. Final Provisions

This Arrangement takes effect on the date it is signed by both Participants and remains in effect for a period of 5 years unless either Participant, after due consideration, provides an official three-month advance notice to the other Participant of its desire to terminate the Arrangement. Early termination of the present Arrangement would not affect the progress and conclusion of specific activities.

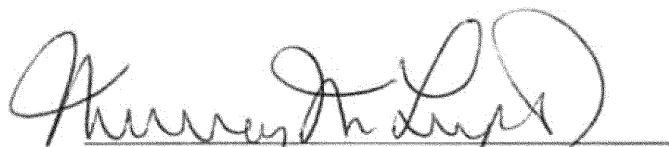
The performance of specific activities may be subject to additional documentation or application procedures as decided or as required by the Participants.

The terms of this Arrangement may be amended only by mutual written consent of the Participants, with such amendments appended hereto.

The present Agreement may be extended for additional periods, as decided to by the Participants following an analysis on the achieved results three months prior to its conclusion. Renewals may be achieved by means of an Addendum appended hereto.

This Arrangement is not intended to create obligations under international or other law.

Signed on behalf of FDA:


Murray M. Lumpkin, M.D., M.Sc.

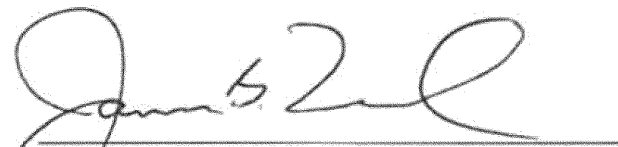
Deputy Commissioner
International Programs

Food and Drug Administration
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UNITED STATES OF AMERICA

Tel: +1.301.796.8400
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Date: 4-5-2011
April 5, 2011

Signed on behalf of IICA:


James French

Director
Technical Cooperation

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Date: 04-15-2011
April 15-2011