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(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 13, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-9095 Filed 4-19-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Risk Communication Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Risk Communication Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 6, 2010, from 8 a.m. to 5 p.m. and May 7, 2010, from 8 a.m. to 2 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center (rm. 1503), Silver Spring, MD 20993. Please note that all visitors must park in the visitors' parking lot near Building 22 (for a campus map, see <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/default.htm>). The Campus is also served by several bus lines connecting to metro rail (see <http://www.wmata.com/>).

Contact Person: Lee L. Zwanziger, Office of the Commissioner, Office of Policy, Planning and Preparedness, Office of Planning, Food and Drug Administration, 5600 Fishers Lane, rm. 14-90, Rockville, MD 20857, 301-827-2895, FAX: 301-827-4050, e-mail: RCAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-

741-8138 (301-443-0572 in the Washington, DC area), code 8732112560. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On May 6 and 7, 2010, the Committee will review the state of current research in a range of fields relevant to improving risk communication at FDA, and discuss applications or gaps for strategic planning of risk communication at FDA. For more specific agenda information, please visit the following Web site and scroll down to the appropriate advisory committee link (<http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>), or call FDA Advisory Committee Information Line as listed above in the *Contact Person* section of the notice. FDA intends to make agenda information available at both these locations no later than 15 days before the meeting.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Visitors to the White Oak Campus must have a valid driver's license or other picture ID, and must enter through Building 1. In order to help speed entrance through security, we request that attendees send an email giving their full names to RCAC@fda.hhs.gov with the word "registration" in the subject line, or telephone Lee Zwanziger (see *Contact Person*), by April 27, 2010.

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 3, 2010. Oral presentations from the public will be scheduled between approximately 3:15 p.m. and 4:15 p.m. on May 6, 2010, and between 1 p.m. and

1:30 p.m. on May 7, 2010. Those desiring to make formal oral presentations should notify Lee Zwanziger and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 27, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 28, 2010.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee 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 contact Lee Zwanziger at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 14, 2010.

Jill H. Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010-9056 Filed 4-19-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Re-Designation of the Service Delivery Area for the Cowlitz Indian Tribe

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: This Notice advises the public that the Indian Health Service (IHS) proposes to expand the geographic boundaries of the Service Delivery Area

(SDA) for the Cowlitz Indian Tribe. The Cowlitz SDA currently is comprised of Clark, Cowlitz, King, Lewis, Pierce, Skamania, and Thurston in the State of Washington. These counties were designated as the Tribe's SDA in 67 FR 46329. It is proposed that Columbia County, Oregon, and Wahkiakum and Kittitas Counties, Washington be added to the existing SDA.

DATES: This notice is effective 30 days after date of publication in the **Federal Register**.

ADDRESSES: Comments may be mailed to Betty Gould, Regulations Officer, Indian Health Service, Suite 450, 12300 Twinbrook Parkway, Rockville, Maryland 20852. Comments will be made available for public inspection at this address from 8:30 a.m. to 5 p.m. Monday–Friday beginning approximately 2 weeks after publication of this notice.

FOR FURTHER INFORMATION CONTACT: Carl Harper, Director, Office of Resource Access and Partnerships, Indian Health Service, Suite 360, 12300 Twinbrook Parkway, Rockville, Maryland 20852. Telephone 301/443-2694 (This is not a toll free number).

SUPPLEMENTARY INFORMATION: The IHS currently provides services under regulations in effect on September 15, 1987 and IHS republished at 42 CFR part 136, subparts A–C. Subpart C defines a Contract Health Service Delivery Area (CHSDA) as the geographic area within which CHS will be made available by the IHS to members of an identified Indian community who reside in the area. Residence with a CHSDA or SDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12, creates no legal entitlement to contract health services but only potential eligibility for services. Services needed but not available at a IHS/Tribal facility are provided under the CHS program depending on the availability of funds, the person's relative medical priority, and the actual availability and accessibility of alternate resources in accordance with the regulations.

As applicable to the Tribes, these regulations provide that, unless otherwise designated, a CHSDA shall

consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation (42 CFR 136.22(a)(6) (2007)). The regulations also provide that after consultation with the Tribal governing body or bodies of those reservations included in the CHSDA, the Secretary may, from time to time, re-designate areas within the United States for inclusion in or exclusion from a CHSDA. The regulations require that certain criteria must be considered before any re-designation is made. The criteria are as follows:

- (1) The number of Indians residing in the area proposed to be so included or excluded;
- (2) Whether the Tribal governing body has determined that Indians residing in the area near the reservation are socially and economically affiliated with the Tribes;
- (3) The geographic proximity to the reservation of the area whose inclusion or exclusion is being considered; and
- (4) The level of funding which would be available for the provision of contract health services.

Additionally, the regulations require that any re-designation of a CHSDA must be made in accordance with the Administrative Procedures Act (5 U.S.C. 553). In compliance with this requirement, we are publishing this proposal and requesting public comment.

The purpose of this FR notice is to notify the public of the request of the Cowlitz Indian Tribe to expand their SDA as presented in their 08–3 Tribal resolution dated January 5, 2008, and 08–56 Tribal resolution, dated December 06, 2008. The Tribe's request will expand their current SDA which incorporates Cowlitz, Clark, Skamania, King, Pierce, Thurston and Lewis Counties in the State of Washington, to include Columbia County in the State of Oregon, and Kittitas and Wahkiakum Counties in the State of Washington.

Under 42 CFR 136.23 those otherwise eligible Indians who do not reside on a reservation but reside within a CHSDA must be either members of the Tribe or maintain close economic and social ties with the Tribe. In this case, the Tribe estimates the current eligible population

will be increased by 35 individuals' enrolled Cowlitz members who are actively involved with the Tribe, but not eligible for health services.

In applying the aforementioned CHSDA re-designation criteria required by operative regulations (43 FR 35654), the following findings are made:

1. Columbia County, Oregon is contiguous with Clark County in the state of Washington. Kittitas County is contiguous to King County and Wahkiakum County is contiguous to Lewis in the State of Washington.
2. These three counties are not part of any other Tribes CHSDA.
3. It is important for the Cowlitz Indian Tribe to be able to deliver health care services to enrolled members residing in these three counties. The Tribe believes eligible Tribal members living in the counties proposed for expansion should also be eligible for CHS.
4. Most of the 35 Tribal members use the Cowlitz Clinic in Longview, Washington for their health care needs. It is estimated that members have a 40 minute drive to receive their health care. These Tribal members do not currently receive care under the CHS program.

5. The financial resources required to meet the immediate needs of the Tribal members residing in the three counties will not be substantial as the Tribe will use existing Federal allocations for contract health funds.

Since CHS is a critical component of the Tribes' overall health care system for its members, the Tribe feels that the members residing in the three counties should be included within the SDA for the Tribe.

Accordingly, after considering the Tribes' request in light of the criteria specified in the regulations, the IHS is proposing to re-designate the SDA for the Tribe to consist of Columbia County in the State of Oregon and Kittitas and Wahkiakum Counties in the State of Washington.

This notice does not contain reporting or recordkeeping requirements subject to prior approval by the Office of Management and Budget under the Paperwork Reduction Act of 1980.

CONTRACT HEALTH SERVICE DELIVERY AREAS AND SERVICE DELIVERY AREAS

Tribe/reservation	County/state
Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona.	Pinal, AZ.
Alabama-Coushatta Tribes of Texas	Polk, TX. ¹
Alaska	Entire State. ²
Arapaho Tribe of the Wind River Reservation, Wyoming	Hot Springs, WY, Fremont, WY, Sublette, WY.
Aroostook Band of Micmac Indians of Maine	Aroostook, ME. ³

CONTRACT HEALTH SERVICE DELIVERY AREAS AND SERVICE DELIVERY AREAS—Continued

Tribe/reservation	County/state
Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana.	Daniels, MT, McCone, MT, Richland, MT, Roosevelt, MT, Sheridan, MT, Valley, MT.
Bad River Band of the Lake Superior Tribe of Chippewa Indians of the Bad River Reservation, Wisconsin.	Ashland, WI, Iron, WI.
Bay Mills Indian Community, Michigan	Chippewa, MI.
Blackfeet Tribe of the Blackfeet Indian Reservation of Montana	Glacier, MT, Pondera, MT.
Minnesota Chippewa Tribe, Minnesota Bois Forte Band (Nett Lake)	Itasca, MN, Koochiching, MN, St. Louis, MN.
Brigham City Intermountain School Health Center, Utah	4
Burns Paiute Tribe of the Burns Paiute Indian Colony of Oregon	Harney, OR.
California	Entire State, except for the counties listed in the footnote. ⁵
Catawba Indian Nation of South Carolina	All Counties in SC, ⁶ Cabarrus, NC, Cleveland, NC, Gaston, NC, Mecklenburg, NC, Rutherford, NC, Union, NC.
Cayuga Nation of New York	Allegany, NY, ⁷ Cattaraugus, NY, Chautaugua, NY, Erie, NY, Warren, PA.
Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota.	Corson, SD, Dewey, SD, Haakon, SD, Meade, SD, Perkins, SD, Potter, SD, Stanley, SD, Sully, SD, Walworth, SD, Ziebach, SD.
Chippewa-Cree Indians of the Rocky Boy's Reservation, Montana	Chouteau, MT, Hill, MT, Liberty, MT.
Chitimacha Tribe of Louisiana	St. Mary Parish, LA.
Cocopah Tribe of Arizona	Yuma, AZ, Imperial, CA.
Coeur D'Alene Tribe of the Coeur D'Alene Reservation, Idaho	Benewah, ID, Kootenai, ID, Latah, ID, Spokane, WA, Whitman, WA.
Colorado River Indian Tribes of the Colorado River Indian Reservation, Arizona and California.	La Paz, AZ, Riverside, CA, San Bernardino, CA, Yuma, AZ.
Confederated Salish & Kootenai Tribes of the Flathead Reservation, Montana.	Flathead, MT, Lake, MT, Missoula, MT, Sanders, MT.
Confederated Tribes of the Chehalis Reservation, Washington	Grays Harbor, WA, Lewis, WA, Thurston, WA.
Confederated Tribes of the Colville Reservation, Washington	Chelan, WA, ⁸ Douglas, WA, Ferry, WA, Grant, WA, Lincoln, WA, Okanogan, WA, Stevens, WA.
Confederated Tribes of Coos, Lower Umpqua & Siuslaw Indians of Oregon.	Coos, OR, ⁹ Curry, OR, Douglas, OR, Lane, OR, Lincoln, OR.
Confederated Tribes of the Goshute Reservation, Nevada and Utah	Nevada, Juab, UT, Toole, UT.
Confederated Tribes of Grand Ronde Community of Oregon	Polk, OR, ¹⁰ Washington, OR, Marion, OR, Yamhill, OR, Tillamook, OR, Multnomah, OR.
Confederated Tribes of the Siletz Reservation, Oregon	Benton, OR, ¹¹ Clackamas, OR, Lane, OR, Lincoln, OR, Linn, OR, Marion, OR, Multnomah, OR, Polk, OR, Tillamook, OR, Washington, OR, Yam Hill, OR.
Confederated Tribes of the Umatilla Reservation, Oregon	Umatilla, OR, Union, OR.
Confederated Tribes of the Warm Springs Reservation of Oregon	Clackamas, OR, Jefferson, OR, Linn, OR, Marion, OR, Wasco, OR.
Confederated Tribes & Bands of the Yakama Nation, Washington	Klickitat, WA, Lewis, WA, Skamania, WA, ¹² Yakima, WA.
Coquille Tribe of Oregon	Coos, OR, Curry, OR, Douglas, OR, Jackson, OR, Lane, OR.
Coushatta Tribe of Louisiana	Allen Parish, LA, Elton, LA. ¹³
Cow Creek Band of Umpqua Indians of Oregon	Coos, OR, ¹⁴ Deshutes, OR, Douglas, OR, Jackson, OR, Josephine, OR, Klamath, OR, Lane, OR.
Cowlitz Indian Tribe, Washington	Clark, WA, Cowlitz, WA, King, WA, Lewis, WA, Pierce, WA, Skamania, WA, Thurston, WA, Columbia, OR, Kitititas, WA, Wahkiakum, WA. ¹⁵
Crow Tribe of Montana	Big Horn, MT, Carbon, MT, Treasure, MT, ¹⁶ Yellowstone, MT, Big Horn, WY, Sheridan, WY.
Crow Creek Sioux Tribe of the Crow Creek Reservation, South Dakota	Brule, SD, Buffalo, SD, Hand, SD, Hughes, SD, Hyde, SD, Lyman, SD, Stanley, SD.
Eastern Band of Cherokee Indians of North Carolina	Cherokee, NC, Graham, NC, Haywood, NC, Jackson, NC, Swain, NC.
Flandreau Santee Sioux Tribe of South Dakota	Moody, SD.
Fond du Lac Band of Chippewa Indians of Minnesota	Carlton, MN, St. Louis, MN.
Forest County Potawatomi Community, Wisconsin	Forest, WI, Marinette, WI, Oconto, WI.
Fort Belknap Indian Community of the Fort Belknap Reservation of Montana.	Blaine, MT, Phillips, MT.
Fort McDermitt Paiute and Shoshone Tribes of the Fort McDermitt Indian Reservation, Nevada and Oregon.	Nevada, Malheur, OR.
Fort McDowell Yavapai Nation, Arizona	Maricopa, AZ.
Fort Mojave Indian Tribe of Arizona, California and Nevada	Nevada, Mohave, AZ, San Bernardino, CA.
Gila River Indian Community of the Gila River Indian Reservation, Arizona.	Maricopa, AZ, Pinal, AZ.
Grand Portage Band of Chippewa Indians of Minnesota	Cook, MN.
Grand Traverse Band of Ottawa & Chippewa Indians of Michigan	Antrim, MI, ¹⁷ Benzie, MI, Charlevoix, MI, Grand Traverse, MI, Leelanau, MI, Manistee, MI.
Hannahville Indian Community, Michigan	Delta, MI, Menominee, MI.
Haskell Indian Health Center	Douglas, KS. ¹⁸
Havasupai Tribe of the Havasupai Reservation, Arizona	Coconino, AZ.
Ho-Chunk Nation of Wisconsin	Adams, WI, ¹⁹ Clark, WI, Columbia, WI, Crawford, WI, Dane, WI, Eau Claire, WI, Houston, MN, Jackson, WI, Juneau, WI, La Crosse, WI, Marathon, WI, Monroe, WI, Sauk, WI, Shawano, WI, Vernon, WI, Wood, WI.
Hoh Indian Tribe of the Hoh Indian Reservation, Washington	Jefferson, WA.

CONTRACT HEALTH SERVICE DELIVERY AREAS AND SERVICE DELIVERY AREAS—Continued

Tribe/reservation	County/state
Hopi Tribe of Arizona	Apache, AZ, Coconino, AZ, Navajo, AZ.
Houlton Band of Maliseet Indians of Maine	Aroostook, ME. ²⁰
Hualapai Indian Tribe of the Hualapai Indian Reservation, Arizona	Coconino, AZ, Mohave, AZ, Yavapai, AZ.
Huron Potawatomi, Inc., Michigan	Allegan, MI, ²¹ Barry, MI, Branch, MI, Calhoun, MI, Kalamazoo, MI, Kent, MI, Ottawa, MI.
Iowa Tribe of Kansas and Nebraska	Brown, KS, Doniphan, KS, Richardson, NE.
Jamestown S'Klallam Tribe of Washington	Clallam, WA, Jefferson, WA.
Jena Band of Choctaw Indians, Louisiana	Grand Parish, LA, ²² LaSalle Parish, LA, Rapides Parish, LA.
Jicarilla Apache Nation, New Mexico	Archuleta, CO, Rio Arriba, NM, Sandoval, NM.
Kaibab Band of Paiute Indians of the Kaibab Indian Reservation, Arizona.	Coconino, AZ, Mohave, AZ, Kane, UT.
Kalispel Indian Community of the Kalispel Indian Reservation, Washington.	Pend Oreille, WA, Spokane, WA.
Keweenaw Bay Indian Community, Michigan	Baraga, MI, Houghton, MI, Ontonagon, MI.
Kickapoo Tribe of Indians of the Kickapoo Reservation of Kansas	Brown, KS, Jackson, KS.
Kickapoo Traditional Tribe of Texas	Maverick, TX. ²³
Klamath Tribes of Oregon	Klamath, OR. ²⁴
Kootenai Tribe of Idaho	Boundary, ID.
Lac Courte Oreilles Band of Lake Superior Chippewa Indians of Wisconsin.	Sawyer, WI.
Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation of Wisconsin.	Iron, WI, Oneida, WI, Vilas, WI.
Lac Vieux Desert Band of Lake Superior Chippewa Indians, Michigan ..	Gogebic, MI.
Leech Lake Band of Chippewa Indians of Minnesota	Beltrami, MN, Cass, MN, Hubbard, MN, Itasca, MN.
Little River Band of Ottawa Indians, Michigan	Kent, MI, ²⁵ Muskegon, MI, Newaygo, MI, Oceana, MI, Ottawa, MI, Manistee, MI, Mason, MI, Wexford, MI, Lake, MI.
Little Traverse Bay Bands of Odawa Indians, Michigan	Alcona, MI, ²⁶ Alger, MI, Alpena, MI, Antrim, MI, Benzie, MI, Charlevoix, MI, Cheboygan, MI, Chippewa, MI, Crawford, MI, Delta, MI, Emmet, MI, Grand Traverse, MI, Iosco, MI, Kalkaska, MI, Leelanau, MI, Luce, MI, Mackinac, MI, Manistee, MI, Missaukee, MI, Montmorency, MI, Ogemaw, MI, Oscoda, MI, Otsego, MI, Presque Isle, MI, Schoolcraft, MI, Roscommon, MI, Wexford, MI.
Lower Brule Sioux Tribe of the Lower Brule Reservation, South Dakota	Brule, SD, Buffalo, SD, Hughes, SD, Lyman, SD, Stanley, SD.
Lower Elwha Tribal Community of the Lower Elwha Reservation, Washington.	Clallam, WA.
Lower Sioux Indian Community in the State of Minnesota	Redwood, MN, Renville, MN.
Lummi Tribe of the Lummi Reservation, Washington	Whatcom, WA.
Makah Indian Tribe of the Makah Reservation, Washington	Clallam, WA.
Mashantucket Pequot Tribe of Connecticut	New London, CT. ²⁷
Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan	Allegan, MI, ²⁸ Barry, MI, Kalamazoo, MI, Kent, MI, Ottawa, MI.
Menominee Indian Tribe of Wisconsin	Langlade, WI, Menominee, WI, Oconto, WI, Shawano, WI.
Mescalero Apache Tribe of the Mescalero Reservation, New Mexico	Chaves, NM, Lincoln, NM, Otero, NM.
Miccosukee Tribe of Indians of Florida	Broward, FL, Collier, FL, Miami-Dade, FL, Hendry, FL.
Mille Lacs Band of Chippewa Indians of Minnesota	Aitkin, MN, Kanebec, MN, Mille Lacs, MN, Pine, MN.
Mississippi Band of Choctaw Indians, Mississippi	Attala, MS, Jasper, MS, ²⁹ Jones, MS, Kemper, MS, Leake, MS, Neshoba, MS, Newton, MS, Noxubee, MS, ³⁰ Scott, MS, ³¹ Winston, MS.
Mohegan Indian Tribe of Connecticut	Fairfield, CT, Hartford, CT, Litchfield, CT, Middlesex, CT, New Haven, CT, New London, CT, Tolland, CT, Windham, CT.
Muckleshoot Indian Tribe of the Muckleshoot Reservation, Washington	King, WA, Pierce, WA.
Narragansett Indian Tribe of Rhode Island	Washington, RI. ³²
Navajo Nation, Arizona, New Mexico and Utah	Apache, AZ, Bernalillo, NM, Cibola, NM, Coconino, AZ, Kane, UT, McKinley, NM, Montezuma, CO, Navajo, AZ, Rio Arriba, NM, Sandoval, NM, San Juan, NM, San Juan, UT, Socorro, NM, Valencia, NM.
Nevada	Entire State. ³³
Nez Perce Tribe of Idaho	Clearwater, ID, Idaho, ID, Latah, ID, Lewis, ID, Nez Perce, ID.
Nisqually Indian Tribe of the Nisqually Reservation, Washington	Pierce, WA, Thurston, WA.
Nooksack Indian Tribe of Washington	Whatcom, WA.
Northern Cheyenne Tribe Northern Cheyenne Indian Reservation, Montana.	Big Horn, MT, Carter, MT, ³⁴ Rosebud, MT.
Northwestern Band of Shoshoni Nation of Utah (Washakie)	Box Elder, UT. ³⁵
Oglala Sioux Tribe of the Pine Ridge Reservation, South Dakota	Bennett, SD, Cherry, NE, Custer, SD, Dawes, NE, Fall River, SD, Jackson, SD, ³⁶ Mellele, SD, Pennington, SD, Shannon, SD, Sheridan, NE, Todd, SD.
Oklahoma	Entire State. ³⁷
Omaha Tribe of Nebraska	Burt, NE, Cuming, NE, Monona, IA, Thurston, NE, Wayne, NE.
Oneida Nation of New York	Chenango, NY, Cortland, NY, Herkimer, NY, Madison, NY, Oneida, NY, Onondaga, NY.
Oneida Tribe of Indians of Wisconsin	Brown, WI, Outagamie, WI.
Onondaga Nation of New York	Onondaga, NY.
Paiute Indian Tribe of Utah	Iron, UT, ³⁸ Millard, UT, Sevier, UT, Washington, UT.

CONTRACT HEALTH SERVICE DELIVERY AREAS AND SERVICE DELIVERY AREAS—Continued

Tribe/reservation	County/state
Pascua Yaqui Tribe of Arizona	Pima, AZ. ³⁹
Passamaquoddy Tribe of Maine	Aroostook, ME, ⁴⁰ Washington, ME.
Passamaquoddy Tribe of Pleasant Point, Maine	Washington, ME, south of State Route 9. ⁴¹
Penobscot Tribe of Maine	Aroostook, ME, ⁴² Penobscot, ME.
Poarch Band of Creek Indians of Alabama	Baldwin, AL, ⁴³ Escambia, AL, Mobile, AL, Monroe, AL, Escambia, FL.
Pokagon Band of Potawatomi Indians, Michigan and Indiana	Allegan, MI, Berrien, MI, Cass, MI, Elkhart, IN, ⁴⁴ Kosciusko, IN, La Porte, IN, Marshall, IN, St. Joseph, IN, Starke, IN, Van Buren, MI.
Ponca Tribe of Nebraska	Boyd, NE, ⁴⁵ Burt, NE, Charles Mix, SD, Douglas, NE, Hall, NE, Holt, NE, Knox, NE, Lancaster, NE, Madison, NE, Platte, NE, Pottawattomie, IA, Sarpy, NE, Stanton, NE, Wayne, NE, Woodbury, IA.
Port Gamble Indian Community of the Port Gamble Reservation, Washington.	Kitsap, WA.
Prairie Band of Potawatomi Nation, Kansas	Jackson, KS.
Prairie Island Indian Community in the State of Minnesota	Goodhue, MN.
Pueblo of Acoma, New Mexico	Cibola, NM.
Pueblo of Cochiti, New Mexico	Sandoval, NM, Sante Fe, NM.
Pueblo of Jemez, New Mexico	Sandoval, NM.
Pueblo of Isleta, New Mexico	Bernalillo, NM, Torrance, NM, Valencia, NM.
Pueblo of Laguna, New Mexico	Bernalillo, NM, Cibola, NM, Sandoval, NM, Valencia, NM.
Pueblo of Nambe, New Mexico	Santa Fe, NM.
Pueblo of Picuris, New Mexico	Taos, NM.
Pueblo of Pojoaque, New Mexico	Rio Arriba, NM, Santa Fe, NM.
Pueblo of San Felipe, New Mexico	Sandoval, NM.
Pueblo of San Ildefonso, New Mexico	Los Alamos, NM, Rio Arriba, NM, Sandoval, NM, Santa Fe, NM.
Pueblo of San Juan, New Mexico	Rio Arriba, NM.
Pueblo of Sandia, New Mexico	Bernalillo, NM, Sandoval, NM.
Pueblo of Santa Ana, New Mexico	Sandoval, NM.
Pueblo of Santa Clara, New Mexico	Los Alamos, NM, Sandoval, NM, Santa Fe, NM.
Pueblo of Santo Domingo, New Mexico	Sandoval, NM, Santa Fe, NM.
Pueblo of Taos, New Mexico	Colfax, NM, Taos, NM.
Pueblo of Tesuque, New Mexico	Santa Fe, NM.
Pueblo of Zia, New Mexico	Sandoval, NM.
Puyallup Tribe of the Puyallup Reservation, Washington	King, WA, Pierce, WA, Thurston, WA.
Quechan Tribe of the Fort Yuma Indian Reservation, California and Arizona.	Yuma, AZ, Imperial, CA.
Quileute Tribe of the Quileute Reservation, Washington	Clallam, WA, Jefferson, WA.
Quinault Tribe of the Quinault Reservation, Washington	Grays Harbor, WA, Jefferson, WA.
Rapid City, South Dakota	Pennington, SD. ⁴⁶
Red Cliff Band of Lake Superior Chippewa Indians of Wisconsin	Bayfield, WI.
Red Lake Band of Chippewa Indians, Minnesota	Beltrami, MN, Clearwater, MN, Koochiching, MN, Lake of the Woods, MN, Marshall, MN, Pennington, MN, Polk, MN, Roseau, MN.
Rosebud Sioux Tribe of the Rosebud Indian Reservation. South Dakota	Bennett, SD, Cherry, NE, Gregory, SD, Lyman, SD, Mellette, SD, Todd, SD, Tripp, SD.
Sac & Fox Tribe of the Mississippi in Iowa	Tama, IA.
Sac & Fox Nation of Missouri in Kansas & Nebraska	Brown, KS, Richardson, NE.
Saginaw Chippewa Indian Tribe of Michigan	Arenac, MI, ⁴⁷ Clare, MI, Isabella, MI, Midland, MI, Missaukee, MI.
St. Croix Chippewa Indians of Wisconsin	Barron, WI, Burnett, WI, Pine, MN, Polk, WI, Washburn, WI.
Saint Regis Mohawk Tribe, New York	Franklin, NY, St. Lawrence, NY.
Salt River Pima-Maricopa Indian Community of Salt River Reservation, Arizona.	Maricopa, AZ.
Samish Indian Tribe, Washington	Clallam, WA, ⁴⁸ Island, WA, Jefferson, WA, King, WA, Kitsap, WA, Pierce, WA, San Juan, WA, Skagit, WA, Snohomish, WA, Whatcom, WA.
San Carlos Apache Tribe of the San Carlos Reservation, Arizona	Apache, AZ, Cochise, AZ, Gila, AZ, Graham, AZ, Greenlee, AZ, Pinal, AZ.
San Juan Southern Paiute Tribe of Arizona	Coconino, AZ, San Juan, UT.
Santee Sioux Nation, Nebraska	Bon Homme, SD, Knox, NE.
Sauk-Suiattle Indian Tribe of Washington	Snohomish, WA, Skagit, WA.
Sault Ste. Marie Tribe of Chippewa Indians of Michigan	Alger, MI, ⁴⁹ Chippewa, MI, Delta, MI, Luce, MI, Mackinac, MI, Marquette, MI, Schoolcraft, MI.
Seminole Tribe of Florida	Broward, FL, Collier, FL, Miami-Dade, FL, Glades, FL, Hendry, FL.
Seneca Nation of New York	Allegany, NY, Cattaraugus, NY, Chautaugua, NY, Erie, NY, Warren, PA.
Shakopee Mdewakanton Sioux Community of Minnesota	Scott, MN.
Shoalwater Bay Tribe of the Shoalwater Bay Indian Reservation, Washington.	Pacific, WA.
Shoshone Tribe of the Wind River Reservation, Wyoming	Hot Springs, WY, Fremont, WY, Sublette, WY.
Shoshone-Bannock Tribes of the Fort Hall Reservation of Idaho	Bannock, ID, Bingham, ID, Caribou, ID, Lemhi, ID, ⁵⁰ Power, ID.
Shoshone-Paiute Tribes of the Duck Valley Reservation, Nevada	Nevada, Owyhee, ID.
Sisseton-Wahpeton Oyate of the Lake Traverse Reservation, South Dakota.	Codington, SD, Day, SD, Grant, SD, Marshall, SD, Richland, ND, Roberts, SD, Sargent, ND, Traverse, MN.

CONTRACT HEALTH SERVICE DELIVERY AREAS AND SERVICE DELIVERY AREAS—Continued

Tribe/reservation	County/state
Skokomish Indian Tribe of Skokomish Reservation, Washington	Mason, WA.
Skull Valley Band of Goshute Indians of Utah	Tooele, UT.
Snoqualmie Tribe, Washington	King, WA, ⁵¹ Snohomish, WA, Pierce, WA, Island, WA, Mason, WA.
Sokaogon Chippewa Community, Wisconsin	Forest, WI.
Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado ..	Archuleta, CO, La Plata, CO, Montezuma, CO, Rio Arriba, NM, San Juan, NM.
Spirit Lake Tribe, North Dakota	Benson, ND, Eddy, ND, Nelson, ND, Ramsey, ND.
Spokane Tribe of the Spokane Reservation, Washington	Ferry, WA, Lincoln, WA, Stevens, WA.
Squaxin Island Tribe of the Squaxin Island Reservation, Washington	Mason, WA.
Standing Rock Sioux Tribe of North and South Dakota	Adams, ND, Campbell, SD, Corson, SD, Dewey, SD, Emmons, ND, Grant, ND, Morton, ND, Perkins, SD, Sioux, ND, Walworth, SD, Ziebach, SD.
Stockbridge Munsee Community, Wisconsin	Menominee, WI, Shawano, WI.
Stillaguamish Tribe of Washington	Snohomish, WA.
Suquamish Indian Tribe of the Port Madison Reservation, Washington	Kitsap, WA.
Swinomish Indians of the Swinomish Reservation, Washington	Skagit, WA.
Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota ..	Dunn, ND, Mercer, ND, McKenzie, ND, McLean, ND, Mountrail, ND, Ward, ND.
Tohono O'odham Nation of Arizona	Maricopa, AZ, Pima, AZ, Pinal, AZ.
Tonawanda Band of Seneca Indians of New York	Genesee, NY, Erie, NY, Niagara, NY.
Tonto Apache Tribe of Arizona	Gila, AZ.
Trenton Service Unit, North Dakota and Montana	Divide, ND, ⁵² McKenzie, ND, Williams, ND, Richland, MT, Roosevelt, MT, Sheridan, MT.
Tulalip Tribes of the Tulalip Reservation, Washington	Snohomish, WA.
Tunica-Biloxi Indian Tribe of Louisiana	Avoyelles, LA, Rapides, LA. ⁵³
Turtle Mountain Band of Chippewa Indians of North Dakota	Rolette, ND.
Tuscarora Nation of New York	Niagara, NY.
Upper Sioux Community, Minnesota	Chippewa, MN, Yellow Medicine, MN.
Upper Skagit Indian Tribe of Washington	Skagit, WA.
Ute Indian Tribe of the Uintah & Ouray Reservation, Utah	Carbon, UT, Daggett, UT, Duchesne, UT, Emery, UT, Grand, UT, Rio Blanco, CO, Summit, UT, Uintah, UT, Utah, UT, Wasatch, UT.
Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico and Utah.	Apache, AZ, La Plata, CO, Montezuma, CO, San Juan, NM, San Juan, UT.
Wampanoag Tribe of Gay Head (Aquinnah) of Massachusetts	Dukes, MA. ⁵⁴
Washoe Tribe of Nevada & California	Entire State of NV. Entire State of CA, except for the counties listed in footnote.
White Earth Band of Chippewa Indians of Minnesota	Becker, MN, Clearwater, MN, Mahanomen, MN, Norman, MN, Polk, MN.
White Mountain Apache Tribe of the Fort Apache Reservation, Arizona	Apache, AZ, Coconino, AZ, Gila, AZ, Graham, AZ, Greenlee, AZ, Navajo, AZ.
Winnebago Tribe of Nebraska	Dakota, NE, Dixon, NE, Monona, IA, Thurston, NE, Wayne, NE, Woodbury, IA.
Yankton Sioux Tribe of South Dakota	Bon Homme, SD, Boyde, NE, Charles Mix, SD, Douglas, SD, Gregory, SD, Hutchinson, SD, Knox, NE.
Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona.	Yavapai, AZ.
Yavapai-Prescott Tribe of the Yavapai Reservation, Arizona	Yavapai, AZ.
Ysleta Del Sur Pueblo of Texas	El Paso, TX. ⁵⁵
Zuni Tribe of the Zuni Reservation, New Mexico	Apache, AZ, Cibola, NM, McKinley, NM, Valencia, NM.

¹ Public Law 100-89, Restoration Act for Ysleta Del Sur and Alabama and Coushatta Tribes of Texas establishes service areas for "members of the Tribe" by sections 101(3) and 105(a) for the Pueblo and sections 201(3) and 206(a) respectively.

² Entire State of Alaska is included as a CHSDA by regulation (42 CFR 136.22(a)(1)).

³ Aroostook Band of Micmac was recognized by Congress on November 26, 1991 through the Aroostook Band of Micmac Settlement Act. Aroostook County was defined as the SDA.

⁴ Special programs established by Congress irrespective of the eligibility regulations. Eligibility for services at these facilities is based on the legislative history of the appropriation of funds for the particular facility, rather than the eligibility regulations and historically services have been provided at Brigham City (Public Law 88-358).

⁵ Entire State of California, excluding counties of Alameda, Contra Costa, Los Angeles, Marin, Orange, Sacramento, San Francisco, San Mateo, Santa Clara, Kern, Merced, Monterey, Napa, San Benito, San Joaquin, San Luis Obispo, Santa Cruz, Solano, Stanislaus, and Ventura, is designated a CHSDA (25 U.S.C. 1680).

⁶ This is a newly recognized Tribe, as documented at 67 FR 46329, July 12, 2002. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.

⁷ This is a newly recognized Tribe, as documented at 67 FR 46329, July 12, 2002. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.

⁸ Historically part of the Coleville Service Unit population since 1970.

⁹ Members of the Tribe residing in these counties were specified as eligible for Federal services and benefits without regard to the existence of a Federal Indian reservation (Public Law 98-481, and H. Rept. No. 98-904).

¹⁰ Confederated Tribes of Grande Ronde Community of Oregon recognized by Public Law 98-165, signed into law on November 22, 1983, provides for eligibility in these six counties without regard to the existence of a reservation.

¹¹ In order to carry out the Congressional intent of the Siletz Restoration Act, Public Law 95-195, as expressed in H. Report No. 95-623, at page 4, Siletz Tribal members residing in these counties are eligible for contract health services.

¹² Historically part of the Yakama Service Unit population since 1979.

¹³ Contract Health Service Delivery Area expanded administratively by the Director, IHS, through regulation (42 CFR 136.22(6)) to include city limits of Elton, LA.

¹⁴ Cow Creek Band of Umpqua Indians of Oregon recognized by Public Law 97-391, signed into law on December 29, 1983. House Rept. No. 97-862 designates Douglas, Jackson, and Josephine Counties as a service area without regard to the existence of a reservation. The IHS later exercised administrative discretion to add Coos, Deshutes, Klamath and Lane counties to the service delivery area.

¹⁵ This is a newly recognized Tribe, as documented at 67 FR 46329, July 12, 2002. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638. It is proposed that Columbia County, OR, Kittitas, WA and Wahkiakum County, WA be added to the existing SDA.

¹⁶ Historically part of Crow Service Unit population.

¹⁷ Historically part of the Grande Traverse Service Unit population since 1980.

¹⁸ Historically part of Kansas Service Unit since 1979. Special programs established by Congress irrespective of the eligibility regulations. Eligibility for services at these facilities is based on the legislative history of the appropriation of funds for the particular facility, rather than the eligibility regulations and historically services have been provided at Haskell (H. Rept. No. 95-392).

¹⁹ The counties included in this CHSDA were designated by regulation (42 CFR 136.22(a)(5)).

²⁰ Public Law 97-428 provides for eligibility in or around the Town of Houlton without regard to existence of a reservation.

²¹ This is a newly recognized Tribe, as documented at 67 FR 46329, July 12, 2002. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.

²² This is a newly recognized Tribe, as documented at 67 FR 46329, July 12, 2002. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.

²³ Texas Band of Kickapoo was recognized by Public Law 97-429, signed into law on January 8, 1983. The Act provides for eligibility for Kickapoo Tribal members residing in Maverick County without regard to the existence of a reservation.

²⁴ Legislative history states that for the purpose of Federal services and benefits "members of the tribe residing in Klamath County shall be deemed to be residing in or near a reservation". (Pub. L. 99-398, Sec. 2(2)).

²⁵ The Little River Band of Ottawa Indians and the Little Traverse Bay Bands of Odawa Indians were recognized by Congress (Pub. L. 103-324, Sec. 4 (b)(2)) and the listed counties were designated as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Pub. L. 93-638.

²⁶ The Little River Band of Ottawa Indians and the Little Traverse Bay Bands of Odawa Indians were recognized by Congress (Pub. L. 103-324, Sec. 4 (b)(2)) and the listed counties were designated as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Pub. L. 93-638.

²⁷ Mashantucket Pequot Indian Claims Settlement Act, Public Law 98-134, signed into law on October 18, 1983, provides for a reservation in New London.

²⁸ This is a newly recognized Tribe, as documented at 67 FR 46329, July 12, 2002. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.

²⁹ Choctaw Indians residing in Jasper and Noxubee Counties, MS, will continue to be eligible for contract health services. These two counties were inadvertently omitted from 42 CFR 136.22.

³⁰ Choctaw Indians residing in Jasper and Noxubee Counties, MS, will continue to be eligible for contract health services. These two counties were inadvertently omitted from 42 CFR 136.22.

³¹ Historically part of the Choctaw Service Unit population since 1970.

³² Narragansett Indians recognized by Public Law 95-395, signed into law September 30, 1978. Lands in Washington County are now Federally restricted and the Bureau of Indian Affairs considers them as the Narragansett Indian Reservation.

³³ Entire State of Nevada is included as a CHSDA by regulation (42 CFR 136.22(a)(2)).

³⁴ Historically part of the Northern Cheyenne Service Unit population since 1979.

³⁵ Land of Box Elder County, Utah, taken into trust for the Tribe in 1986.

³⁶ Washabaugh County, SD is part of Jackson County, SD, on November 5, 1968.

³⁷ Entire State of Oklahoma is included as a CHSDA by regulation (42 CFR 136.22(a)(3)).

³⁸ Paiute Indian Tribe of Utah Reservation Act, Public Law 96-227, provides for the extension of services to these four counties without regard to the existence of a reservation.

³⁹ Legislative history (H.R. Report No. 95-1021) to Public Law 95-375, Extension of Federal Benefits to Pascua Yaqui Indians, Arizona, expresses congressional intent that lands conveyed to the Tribes pursuant to Act of October 8, 1964. (Pub. L. 88-350) shall be deemed a Federal Indian Reservation.

⁴⁰ Included to carry out the intention of Congress to fund and provide contract health services to Penobscot and Passamaquoddy Indians (Pub. L. 96-420; H. Rept. 96-1353).

⁴¹ Included to carry out the intention of Congress to fund and provide contract health services to Penobscot and Passamaquoddy Indians (Pub. L. 96-420; H. Rept. 96-1353).

⁴² Included to carry out the intention of Congress to fund and provide contract health services to Penobscot and Passamaquoddy Indians (Pub. L. 96-420; H. Rept. 96-1353).

⁴³ Counties in the Service Unit designated by Congress for the Poarch Band of Creek Indians (see H. Rept. 98-886, June 29, 1984; Cong. Record, October 10, 1984, Pg. H11929).

⁴⁴ This is a newly recognized Tribe, as documented at 67 FR 46329, July 12, 2002. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.

⁴⁵ Ponca Restoration Act, Public Law 101-484, recognized members of the Tribe residing in Boyd, Douglas, Knox, Madison or Lancaster counties of Nebraska or Charles Mix county of South Dakota shall be deemed to be residing on or near a reservation. Public Law 104-109 added Burt, Hall, Holt, Platte, Sarpy, Stanton, and Wayne counties of Nebraska and Pottawattomie and Woodbury counties of Iowa.

⁴⁶ Special programs established by Congress irrespective of the eligibility regulations. Eligibility for services at these facilities is based on the legislative history of the appropriation of funds for the particular facility, rather than the eligibility regulations and historically services have been provided at Rapid City.

⁴⁷ Historically part of Isabella Reservation Area and Eastern Michigan Service Unit population since 1979.

⁴⁸ This is a newly recognized Tribe, as documented at 67 FR 46329, July 12, 2002. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.

⁴⁹ The counties included in this CHSDA were designated by regulation (42 CFR 136.22(a)(4)).

⁵⁰ Historically part of the Fort Hall Service Unit population since 1979.

⁵¹ This is a newly recognized Tribe, as documented at 67 FR 46329, July 12, 2002. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.

⁵² The Secretary acting through the Service is directed to provide contract health services to Turtle Mountain Band of Chippewa Indians that reside in Trenton Service Area of Divide, Mackenzie, and Williams counties in the state of North Dakota and the adjoining counties of Richland, Roosevelt, and Sheridan in the state of Montana (Sec. 815, Pub. L. 94-437).

⁵³ Historically part of the Tunica Biloxi Service Unit population since 1982.

⁵⁴ Members of the Tribe residing in Martha's Vineyard [are] deemed to be living "on or near an Indian reservation" for purposes of eligibility for Federal services (Sec. 12, Pub. L. 100-95).

⁵⁵ Public Law 100-89, Restoration Act for Ysleta Del Sur and Alabama and Coughatta Tribes of Texas establishes service areas for "members of the Tribe" by sections 101(3) and 105(a) for the Pueblo and sections 201(3) and 206(a) respectively.

Dated: April 8, 2010.

Yvette Roubideaux,

Director, Indian Health Service.

[FR Doc. 2010-8831 Filed 4-19-10; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0195]

Risk Profile: Pathogens and Filth in Spices: Request for Comments and for Scientific Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments and scientific data and information that would assist the agency in its plans to conduct a risk profile for pathogens and filth in spices. The purpose of the risk profile is to ascertain the current state of knowledge about spices contaminated with microbiological pathogens and/or filth, and the effectiveness of current and potential new interventions to reduce or prevent illnesses from contaminated spices.

DATES: Submit electronic or written comments and scientific data and information by June 21, 2010.

ADDRESSES: Submit electronic comments and scientific data and information to <http://www.regulations.gov>. Submit written comments and scientific data and information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sherri B. Dennis, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1914.

SUPPLEMENTARY INFORMATION:

I. Background

A risk profile is a science-based document that describes the current state of knowledge about a specific food safety problem or issue and provides an evaluation of the data and information to support current interventions or new approaches to reduce or prevent illnesses (Ref. 1). FDA has adapted this tool as a new approach to assist the agency in its regulatory decisionmaking. Unlike a quantitative risk assessment,

which provides information about the number of people affected by a hazard in food and how this number might be changed if various control options were implemented, a risk profile provides qualitative answers to questions about the hazard and options for controlling it, based on available data. The information in a risk profile may affect a range of decisions, such as whether or not to commission a quantitative risk assessment or a request for research, or whether or not to implement an immediate and/or provisional regulatory decision. In some cases, it may reveal that no further action is needed.

The risk profile for pathogens and filth in spices will provide information for FDA to use in the development of plans to reduce or prevent illness from spices contaminated by microbial pathogens and/or filth. Concerns regarding the effectiveness of current control measures to reduce or prevent illness from spices have been renewed by recent outbreaks of *Salmonella* associated with spices, including the imported ground white and black pepper products linked to an April 2009 outbreak of *Salmonella* Rissen illness, and the black and red pepper products recalled in March 2010 in response to an outbreak of *Salmonella* Montevideo illness (Refs. 2 and 3).

For the purpose of this risk profile, the term "spice" means any aromatic vegetable substances in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, whose significant function in food is seasoning rather than nutritional, and from which no portion of any volatile oil or other flavoring principle has been removed. The specific hazards in spices to be considered in this risk profile include those microbiological pathogens and filth in spices that are identified in the published literature, outbreaks, recalls, and submissions to the Reportable Food Registry (RFR).¹ For purposes of this risk profile, FDA considers "filth" to mean "extraneous materials" as defined in FDA's Defect Levels Handbook (Ref. 4). The Defect Levels Handbook defines "extraneous materials" as "any foreign matter in a product associated with objectionable conditions or practices in production, storage, or distribution * * * [including] objectionable matter contributed by insects, rodents, and birds; decomposed material; and

¹ The RFR is an electronic portal where responsible parties are required to file a report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals (Ref. 5).

miscellaneous matter such as sand, soil, glass, rust, or other foreign substances."

The overall objectives of the risk profile are to:

- Describe the nature and extent of the public health risk, by identifying the most commonly occurring microbial and filth hazards in spices;
- Describe and evaluate current mitigation and control options;
- Identify potential additional mitigation or control options;
- Identify research needs and data gaps.

The specific questions to be addressed by the risk profile include:

- What is known about the frequency and levels of pathogen and/or filth contamination of spices throughout the food supply chain (e.g., on the farm, at primary processing/manufacturing, intermediary processing (where spices are used as ingredients in multi-component products), distribution (including importation), retail sale/use, and the consumer's home)?
- What is known about differences in production and contamination of imported and domestic spices?
- What is known about the effectiveness, cost, and practicality of currently available and potential future interventions to prevent human illnesses associated with pathogen and/or filth contamination of spices (e.g., practices and/or technologies to reduce or prevent contamination, surveillance, inspection, import strategies, or guidance)?
- What are the highest priority research needs related to prevention or reduction of pathogens and/or filth in spices?

II. Request for Comments and for Scientific Data and Information

FDA is requesting comments on the risk profile approach outlined previously in this document and the submission of scientific data and information relevant to the risk profile. The agency is particularly interested in the following types of information:

1. Data, including unpublished data, on the incidence of contamination in spices according to:
 - a. Date tested,
 - b. Country exporting the spice and/or country of origin if different,
 - c. Type of spice,
 - d. Pathogen(s) and/or filth type (e.g., insect, rodent, extraneous),
 - e. Quantitative (enumeration) or qualitative (presence/absence) results, and
 - f. Other product sample information (e.g., pre- or post-treatment, treatment type, stage of production/processing).