

In the preamble to the final rule, FDA stated that it intended to publish a guidance on applying this rule. In a notice published in the **Federal Register** on February 22, 2001 (66 FR 11172), FDA invited public comments on the topics that should be included in such a guidance. FDA agrees with the comments that were submitted stating that the preamble to the structure/function rule and the numerous courtesy letters that the agency has issued since the enactment of section 403(r)(6) provide considerable guidance to dietary supplement manufacturers about the types of claims that the agency considers to be disease claims. Therefore, FDA has decided not to issue such a guidance at this time. FDA will continue to monitor dietary supplement manufacturers' compliance with section 403(r)(6) of the act and § 101.93, take enforcement action where appropriate, and reconsider the possibility of issuing guidance if future developments warrant.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the substantiation draft guidance document. (FDA is not specifically seeking comment on its decision not to publish additional guidance on the structure/function rule.) Two copies of mailed comments are to be submitted, 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. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.cfsan.fda.gov> or <http://www.fda.gov/dockets/ecomments>. Once on this site, select 2004D-0466 "Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act" and follow the directions. Copies of this draft guidance may be obtained on the Internet from the CFSAN homepage at <http://www.cfsan.fda.gov>.

Dated: October 25, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Border and Transportation Security; Notice to Aliens Included in the United States Visitor and Immigrant Status Indicator Technology System (US-VISIT)

AGENCY: Border and Transportation Security Directorate, DHS.

ACTION: Notice.

SUMMARY: The Department of Homeland Security (Department or DHS) has established the United States Visitor and Immigrant Status Indicator Technology Program (US-VISIT), an integrated, automated entry-exit system that records the arrival and departure of aliens; verifies aliens' identities; and authenticates aliens' travel documents through comparison of biometric identifiers. On August 31, 2004, DHS implemented the second phase of US-VISIT by publishing an interim final rule in the **Federal Register** at 69 FR 53318 authorizing DHS to require certain aliens to provide fingerprints, photographs or other biometric identifiers upon arrival in the United States at the 50 most trafficked land ports of entry. The interim rule also authorized DHS to identify the specific land border ports in a separate notice published in the **Federal Register**.

This notice identifies the 50 most trafficked land ports of entry where US-VISIT will be implemented. The notice further provides an estimated date when each port will begin enrolling aliens in US-VISIT at the secondary inspection area. Pursuant to the August 31, 2004 interim rule, all 50 ports of entry will begin enrolling aliens in US-VISIT no later than December 31, 2004.

In addition, as stated in the August 31, 2004 interim rule, this notice identifies only land ports of entry in which aliens will be enrolled in US-VISIT upon entry into the United States. DHS will announce, through a future notice in the **Federal Register**, the piloting of a biometric data collection program at a limited number of sites as part of US-VISIT processing upon departure from the United States.

FOR FURTHER INFORMATION, CONTACT: Michael Hardin, Senior Policy Advisor, US-VISIT, Border and Transportation Security, Department of Homeland Security, 1616 N. Fort Myer Drive, 18th Floor, Arlington, Virginia 22209, (202) 298-5200.

The 50 Land Border Ports of Entry (POEs) that will begin biometric data collection as part of US-VISIT processing no later than December 31, 2004 are as follows:

Estimated start date of November 15, 2004 (6):

Port Huron POE, Blue Water Bridge, Highway 69 and International Border, Port Huron, Michigan
Douglas POE, Rte 191 and International Border, Douglas, AZ
Lincoln-Juarez Bridge POE, Laredo, TX Gateway to the Americas International Bridge POE, Laredo, TX
Columbia Solidarity Bridge POE, Laredo, TX

World Trade Bridge POE, Laredo, TX
Estimated start date of December 6, 2004 (11):

Niagara Falls POE (to include Lewiston-Queenstown, Whirlpool, and Rainbow Bridges), Niagara Falls, NY
Peace Bridge POE, Moore Drive and International Border, Buffalo, NY
Detroit Ambassador Bridge POE, Detroit, MI
Detroit-Windsor Tunnel POE, Detroit, MI
Lukeville POE, Highway 85 & International Border, Lukeville, AZ
Nogales East (Deconcini POE), Nogales, AZ
Nogales West (Mariposa POE), Nogales, AZ

San Luis POE, Highway 95 & International Border, San Luis, AZ
Andrade POE, Andrade, CA
Calexico East-Imperial Valley POE, Rte 111 and International Border, Calexico, CA
Calexico West POE, Rte 111 and International Border, Calexico, CA
Estimated start date of December 13, 2004 (11):

Fabens POE 18051, Island Guadalupe, Fabens, TX
Presidio POE, Border Station Highway 67, Presidio, TX 79845
Santa Teresa POE, Santa Teresa, NM
Otay Mesa POE, 9777 Via De La Amistad, San Diego, CA
San Ysidro POE, Highway 5 and International Border, San Diego, CA
Tecate POE, Hwy 188 and International Border, Tecate, CA
Blaine-Pacific Highway POE, Rte. 543 and International Border, Blaine, WA
Blaine-Peace Arch POE, Interstate 5 and International Border, Blaine, WA
Lynden POE, Rte. 539 and International Border, Lynden, WA
Point Roberts POE, Tyee Drive and Roosevelt Way, Point Roberts, WA
Sumas POE, Cherry Street and International Avenue, Sumas, WA
Estimated start date of December 20, 2004 (10):

Champlain POE, Highway 87 and International Border, Champlain, NY
Massena POE, Rte. 45 and International Border, Rooseveltown, NY
Thousand Islands POE, Highway 81 and International Border, Alexandria Bay, NY

Sault Ste. Marie POE, The International Bridge, Highway 75 and International Border, Sault Ste. Marie, MI

Bridge of the Americas POE, El Paso, TX

Paso del Norte Bridge POE, El Paso, TX

Ysleta POE, Ysleta-Zaragoza Bridge, El Paso, TX

Derby Line POE, Highway 91 and International Border, Derby Line, VT

Calais—Ferry Point POE, Main Street and International Border, Calais, ME

International Falls POE, Rte 53 and International Border, International Falls, MN

Estimated start date of December 27, 2004 (12):

Gateway International Bridge POE, Brownsville, TX

Brownsville/Matamoros Bridge POE, Brownsville, TX

Hidalgo POE, McAllen-Hidalgo-Reynosa International Bridge, McAllen, TX

Los Indios POE, Free Trade Bridge at Los Indios, Los Indios, TX

Los Tomates/Veterans International Bridge POE, Brownsville, TX

Pharr POE, Pharr-Reynosa International Bridge, Pharr, TX

Progreso POE, Progreso/Nuevo Progreso International Bridge, Progreso, TX

Rio Grande City POE, Starr-Camargo Bridge, Rio Grande City, TX

Roma POE, Roma-Ciudad Miguel Alemán Bridge, Highway 83 and International Border, Roma, TX

Del Rio POE, Del Rio/Cuidad Acuna International Bridge, Garfield Avenue and International Border, Del Rio, TX

Eagle Pass Bridge I POE, Eagle Pass/Piedras Negras Bridge, Highway 57 and International Border, Eagle Pass, TX

Eagle Pass Bridge II POE, Camino Real International Bridge, Highway 57 and International Border, Eagle Pass, TX

DHS has included these dates as estimates only. Should changes occur following the publication of this notice, revised estimated dates can be found on the US-VISIT Web site at <http://www.dhs.gov/us-visit>. All of these listed ports of entry, however, will begin US-VISIT implementation by December 31, 2004.

Dated: October 11, 2004.

Tom Ridge,

Secretary of Homeland Security.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

DEPARTMENT OF DEFENSE

Army Corps of Engineers

Notice of Intent To Prepare an Environmental Impact Statement/ Environmental Impact Report for the South Bay Salt Ponds Restoration Project and the South San Francisco Bay Shoreline Study

AGENCIES: U.S. Fish and Wildlife Service, Interior; U.S. Army Corps of Engineers, Defense.

ACTION: Notice of intent.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, as amended (NEPA), the U.S. Fish and Wildlife Service (USFWS) and the U.S. Army Corps of Engineers (Corps) intend to prepare a joint programmatic Environmental Impact Statement/ Environmental Impact Report (EIS/EIR) to address the potential impacts of the South Bay Salt Ponds Restoration Project and the South San Francisco Bay Shoreline Study, San Francisco Bay, California. The two projects are closely interrelated and proposed planning and actions would be done in coordination with each other. The California Department of Fish and Game (CDFG) will be the lead agency under the California Environmental Quality Act (CEQA).

Federal Lead Agencies Proposed and Connected Actions

The Federal Joint Lead Agencies are proposing to undertake two closely related actions that would help prevent flooding and provide for the restoration of the South Bay Salt Ponds. USFWS proposes to prepare a long-term restoration plan for the South Bay Salt Ponds, which includes managed pond and tidal marsh habitat, as well as flood management and recreation components. The proposed action would provide for implementation of the first phase (Phase 1) of the South Bay Salt Ponds restoration plan. The area of the FWS proposed project falls within the larger scope of the actions the Corps is proposing along South San Francisco Bay shoreline. The Corps is proposing to implement a series of activities for tidal and fluvial flood damage reduction, environmental restoration, and related purposes along the South San Francisco Bay shoreline. The Corps' feasibility study may include most of the components of the South Bay Salt Pond Restoration Project. Thus these interconnected actions are

deserving of one cohesive EIS/EIR analysis.

Two public scoping meetings will be held to solicit comments on the environmental effects of the range of potential projects and the appropriate scope of the EIS/EIR. The public is invited to comment on environmental issues to be addressed in the EIS/EIR during these meetings.

DATES: Written comments from all interested parties are encouraged and must be received on or before December 9, 2004. The first of two public scoping meetings will be held on Tuesday, November 16, 2004, from 7 p.m. to 9 p.m. at the NASA Research Center, Building 943, Moffett Field, California. A second scoping meeting will be held on Wednesday, November 17, 2004, from 7 p.m. to 9 p.m. at Centennial Hall, 22292 Foothill Boulevard, Room 4, in Hayward, California. Persons needing reasonable accommodations in order to attend and participate in the public scoping meetings should contact Tim Corrigan at (510) 286-0325 sufficiently in advance of the meeting to allow time to process the request.

ADDRESSES: Written comments and requests for information should be sent to Margaret Kolar, Refuge Manager, U.S. Fish and Wildlife Service, San Francisco Bay NWR Complex, PO Box 524, Newark, California 94560, or Yvonne LeTellier, Project Manager, U.S. Army Corps of Engineers, 333 Market Street 8th Floor, San Francisco, California 94105-2197. Written comments may also be sent by facsimile to (510) 792-5828, or via e-mail through the public comments link on the South Bay Salt Ponds Restoration Project Web site, at www.southbayrestoration.org/Question_Comment.html. All comments received, including names and addresses, will become part of the administrative record and available to the public.

FOR FURTHER INFORMATION CONTACT: Margaret Kolar, Refuge Manager, U.S. Fish and Wildlife Service, San Francisco Bay NWR Complex, (510) 792-0222, or Yvonne LeTellier, Project Manager, U.S. Army Corps of Engineers, (415) 977-8466. For questions concerning the CEQA process, contact Carl Wilcox, Habitat Conservation Manager, California Department of Fish and Game, Region 3 Headquarters, PO Box 47, Yountville, California, 94559, telephone: (707) 944-5525.

SUPPLEMENTARY INFORMATION: The joint programmatic EIS/EIR will address both the proposed South Bay Salt Ponds Restoration Project and the South San Francisco Bay Shoreline Study. USFWS and the Corps propose to integrate the