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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 02–036–2]

Yucatan Peninsula; Addition to the List of Regions Considered Free of Exotic Newcastle Disease

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations by adding the Mexican States of Campeche, Quintana Roo, and Yucatan to the list of regions considered free of exotic Newcastle disease. We have conducted a risk evaluation and have determined that these three Yucatan Peninsula States have met our requirements for being recognized as free of this disease. This action allows importation into the United States of poultry and poultry products from these regions. We are also adding a certification requirement to ensure that poultry and poultry products from Campeche, Quintana Roo, and Yucatan originate in those States or in any other region recognized by the Animal and Plant Health Inspection Service as free of exotic Newcastle disease and that, prior to export to the United States, such poultry and poultry products are not commingled with poultry and poultry products from regions where exotic Newcastle disease exists.

EFFECTIVE DATE: February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Dr. Hatim Gubara, Staff Veterinarian, Regionalization Evaluation Services Staff, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of certain animals and animal products into the United States in order to prevent the introduction of various animal diseases, such as rinderpest, foot-and-mouth disease (FMD), classical swine fever (CSF), and exotic Newcastle disease (END). Among other things, § 94.6 of the regulations lists regions that are considered to be free of END.

On October 22, 2002, we published in the *Federal Register* (67 FR 64827–64833, Docket No. 02–036–1) a proposal to amend the regulations in § 94.6 by adding the Mexican States of Campeche, Quintana Roo, and Yucatan to the list of regions considered free of END. This proposed rule was intended to allow importation into the United States of poultry and poultry products from these regions. We also proposed to amend § 94.15 to remove references to Campeche, Quintana Roo, and Yucatan because we believed that the requirements specified in that section for transit through the United States of poultry carcasses, parts, or products that are otherwise ineligible for entry into the United States under part 94 would no longer apply to those States if they were listed in § 94.6 as regions considered free of END.

We solicited comments concerning our proposal for 60 days ending December 23, 2002. We did not receive any comments. Therefore, for the reasons given in the proposed rule, we are adopting the changes to § 94.6 described in the previous paragraph.

Upon further consideration, however, we decided not to finalize our proposed changes to § 94.15. Some of the poultry carcasses, parts, or products produced in Campeche, Quintana Roo, and Yucatan for export may be produced in plants that do not meet the standards of the Food Safety Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) as specified in 9 CFR part 381. Such poultry carcasses, parts, or products are eligible to transit through the United States under current § 94.15(c). By not finalizing our proposed changes to § 94.15, we will allow such import-ineligible products to continue transiting the United States under the conditions specified in that section.

A comment we received on another proposed rule also had implications for the current rulemaking. On May 13, 2002, we published in the *Federal Register* (67 FR 31987–31992, Docket No. 01–074–1) a proposal to amend the regulations in §§ 94.9 and 94.10 by adding the Mexican States of Baja California, Baja California Sur, Chihuahua, and Sinaloa to the list of regions considered free of CSF, thus allowing importation into the United States of pork, pork products, live swine, and swine semen from those regions. One of the commenters on that proposal, noting that it appeared likely that most of the pork and pork products exported by the State of Chihuahua were derived from swine raised in other regions, requested more information about where those swine originated. The commenter was concerned that pork intended for export to the United States from Chihuahua could be derived from swine that originated in neighboring CSF-affected regions. Because we shared this concern, we added some safeguards when we published the final rule changing the CSF status of those four Mexican States (68 FR 47835–47842, Docket No. 01–074–2, August 12, 2003).

Issues pertaining to the integrity of products exported from certain disease-free regions to the United States, such as the one discussed by that commenter, have acquired a new salience due to the advent of regionalization. Regionalization has allowed the Animal and Plant Health Inspection Service (APHIS) of the USDA to designate regions, as well as entire countries, as free of such animal diseases as CSF and END. While regionalization has allowed APHIS to exercise more flexibility in regulating and has helped to facilitate trade, it has caused APHIS to reconsider the issue of border controls in some cases. Border controls between high- and low-risk regions within a country or within a larger community, such as the European Union, may not always be equivalent to border controls between nations. There may now exist a greater likelihood that animal products intended for export to the United States from some disease-free regions could be derived from animals that originated in affected regions or that animals or animal products from free regions could be commingled with animals or animal products from affected regions prior to export to the United States. Such

imports could present a risk of introducing animal diseases into this country.

Some sections of the regulations in part 94 do contain provisions aimed at reducing the potential risks posed by the commingling of import-eligible and ineligible animals and animal products prior to export to the United States. Section 94.11 places certain restrictions on meat and other animal products imported from certain regions that are designated in § 94.1 as free of rinderpest and FMD but that (1) supplement their meat supplies via the importation of fresh meat of ruminants or swine from regions affected by those diseases, (2) share a common land border with such regions, or (3) import animals from such regions under conditions less restrictive than would be acceptable for importation into the United States. Section 94.13 has similar provisions for pork and pork products imported from certain regions that are designated in § 94.12(a) as being free of swine vesicular disease but that border or have trading relationships with affected regions. Both of these sections contain requirements for additional certifications that include declarations that certain conditions intended to prevent commingling of animal products intended for export to the United States have been satisfied.

To prevent the commingling of import-eligible and ineligible poultry and poultry products prior to export to the United States, we are adopting an additional certification requirement similar to those in §§ 94.11 and 94.13 for imports from the newly eligible States of Campeche, Quintana Roo, and Yucatan. This requirement will be contained in a new § 94.25.

The introductory text of the new § 94.25 enumerates the risk factors that necessitate placing restrictions on the importation of live poultry, poultry meat, and other poultry products, including ship stores, airplane meals, and baggage containing such meat or animal products, from the Mexican States of Campeche, Quintana Roo, and Yucatan that go beyond those placed on imports from other regions designated in § 94.6 as END-free. Because these Mexican States supplement their meat supplies by the importation of fresh (chilled or frozen) poultry meat from END-affected regions, share common land borders with such regions, or import live poultry from such regions under conditions less restrictive than would be acceptable for importation into the United States, there exists the possibility that live poultry or poultry products that are intended for export to the United States could originate in

affected regions or be commingled with live poultry and poultry products from surrounding END-affected regions. Such imports could present a risk of introducing END into the United States. Therefore, in addition to meeting all applicable requirements of part 93, which contains, among other things, general provisions for the importation of live poultry, and of 9 CFR chapter III, under which are included conditions for importation of poultry products promulgated by the FSIS, live poultry, poultry meat, and other poultry products imported into the United States from Campeche, Quintana Roo, and Yucatan must also satisfy the conditions specified in new § 94.25. As noted earlier, these risk factors are of greater concern now than they were in the past due to the advent of regionalization. In future rulemakings, therefore, we intend to apply the additional certification requirement more broadly to any region that we recognize as free of END but that is subject to these risk factors.

Paragraph (a) of new § 94.25 states that live poultry, poultry meat, and other poultry products from any region designated in the section must be accompanied by an additional certification by a full-time salaried veterinary officer of the Government of Mexico. Upon arrival of the live poultry, poultry meat, or other poultry product in the United States, the certification must be presented to an authorized inspector at the port of arrival.

Paragraph (b) contains requirements for the additional certification for live poultry imported from Campeche, Quintana Roo, and Yucatan. The certification accompanying the live poultry must identify the exporting region of the poultry as a region designated in § 94.6 as free of END at the time the poultry were in the region. In addition, the certification must state that the poultry (1) have not been in contact with poultry or poultry products from any region where END is considered to exist, (2) have not lived in a region where END is considered to exist, and (3) have not transited through a region where END is considered to exist unless moved directly in a sealed means of conveyance with the seal intact upon arrival at the point of destination. These provisions are intended to ensure that the live poultry have originated in an END-free region, have not been commingled with infected poultry or been in contact with infected poultry products either in the region of origin or while in transit prior to export to the United States, and are being exported from an END-free region. At this time, Campeche, Quintana Roo,

and Yucatan, which are the only regions in Mexico that APHIS recognizes as being free of END, are the only regions to which these requirements will apply, but we expect to add more regions, in Mexico and worldwide, to § 94.25 in the future.

Paragraph (c) contains requirements for the additional certification accompanying poultry meat or other poultry products from Campeche, Quintana Roo, and Yucatan. The paragraph includes conditions for slaughter, handling, transiting, and processing that the certification must declare have been satisfied.

Paragraph (c)(1) specifies that the additional certification must state that the poultry meat or other poultry products have been derived from poultry that meet all requirements of § 94.25 and that have been slaughtered in a region designated in § 94.6 as free of END at a federally inspected slaughter plant that is under the direct supervision of a full-time salaried veterinarian of the Government of Mexico and that is approved to export poultry meat and other poultry products to the United States in accordance with the FSIS regulations in 9 CFR 381.196. This provision will help ensure that the poultry meat or other poultry products will only be derived from poultry that are free of END and that slaughtering will take place in establishments and under conditions that meet the standards of the FSIS.

Paragraph (c)(2) specifies that the additional certification must state that the poultry meat or other poultry products have not been in contact with poultry meat or other poultry products from any region where END is considered to exist. This provision will help to ensure that products originating in the three Mexican States will not be commingled in the region of origin with products from END-affected regions.

Paragraph (c)(3) specifies that the additional certification must state that the poultry meat or other poultry products have not transited through a region where END exists unless moved directly in a sealed means of conveyance with the seal intact upon arrival at the point of destination. This provision will help to ensure that poultry meat and other poultry products from Campeche, Quintana Roo, and Yucatan will not be subject to contamination through commingling with END-affected products while transiting through END-affected regions prior to export to the United States.

Finally, paragraph (c)(4) contains requirements for the additional certification that must accompany processed poultry meat or other poultry

products imported from Campeche, Quintana Roo, and Yucatan. The certification must state that the products were processed in a region designated in § 94.6 as free of END in a federally inspected processing plant that is under the direct supervision of a full-time salaried veterinarian of the Government of Mexico. This provision will help to ensure that the products will not be commingled with products from an END-affected region during processing and that the processing will be done under adequate supervision in establishments that are eligible to export poultry products to the United States.

We believe that the safeguards in new § 94.25 will allow for the safe importation of live poultry, poultry meat, and other poultry products from the Mexican States of Campeche, Quintana Roo, and Yucatan.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule with the changes discussed in this document.

Effective Date

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made

effective less than 30 days after publication in the **Federal Register**. This rule adds the Mexican States of Campeche, Quintana Roo, and Yucatan to the list of regions considered free of exotic Newcastle disease. We have determined that approximately 2 weeks are needed to ensure that APHIS personnel at ports of entry receive official notice of this change in the regulations. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be effective 15 days after publication in the **Federal Register**.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This rule amends the regulations by adding the Mexican States of Campeche, Quintana Roo, and Yucatan to the list of regions considered free of END and removing END-related restrictions on the transiting of poultry carcasses, parts, or products from these States through

the United States that would no longer apply. The rule also adds a certification requirement to prevent commingling of products from Campeche, Quintana Roo, and Yucatan with products from END-affected regions prior to export to the United States.

A number of factors may influence how much of the poultry produced in the Yucatan Peninsula will be exported to the United States as a result of this rulemaking. These factors include domestic and international supply of, and demand for, poultry and poultry substitutes, U.S. grain prices, exchange rates, freight rates, the structure (number of large integrated operations versus the number of traditional and semi-traditional operations) of the poultry industry in the Yucatan Peninsula, and the ability of Yucatan Peninsula producers/packers consistently to ship cuts that meet U.S. market specifications.

As shown in table 1, Yucatan Peninsula poultry production peaked at roughly 100,000 metric tons (MTs) in 1997 and consistently accounted for about 8 percent of Mexico's total poultry production from 1992 until 1999, the last year for which data were available.

TABLE 1.—YUCATAN POULTRY PRODUCTION BY STATE 1992–1999 (MTs)

Year	1992	1993	1994	1995	1996	1997	1998	1999
Campeche	4,152	5,821	6,322	6,438	6,679	7,440	6,604	6,784
Quintana Roo	5,124	5,940	5,810	7,043	5,490	5,865	4,685	5,374
Yucatan	63,027	74,311	77,841	83,311	86,485	89,698	79,900	81,470
Total	72,303	86,072	89,884	96,792	98,654	103,003	91,189	93,628
Percentage of Mexico's production	8.05	8.28	7.98	7.54	7.80

Source: Centro de Estadística Agropecuaria/SAGARPA.

Our analysis of poultry production in the Yucatan Peninsula suggests 100,000 MTs as the upper limit for poultry and poultry products that could be made available for export to the United States at this time. The Yucatan Peninsula is a grain and oilseed deficit area. Most of the grains and oilseeds used in poultry production (the single largest and most expensive input in poultry production) are imported from the United States. This dependence on imported grains and oilseeds will tend to limit the growth of the Yucatan Peninsula's poultry production and, consequently, the amount of poultry and poultry products available for export to the United States.

It is far more likely that the actual amount of poultry and poultry products that will be exported to the United States from the Yucatan Peninsula States in the near term as a result of this rulemaking will be significantly less than 100,000 MTs. A general analysis of Mexican poultry production systems suggests that a maximum of 60 to 70 percent of Yucatan Peninsula poultry production might meet U.S. import standards.¹ According to Foreign Agricultural Service attaché reports and Economic Research Service (ERS) analysts, most Yucatan Peninsula production will probably be consumed locally or diverted to the local tourist industry. Because of shipping costs, it is

likely that Mexican producers will only find it profitable to ship breast cuts to the United States. Table 2 shows high and low estimates for possible exports of poultry and poultry products from the Yucatan Peninsula to the United States. As shown in the table, between 18,000 and 52,500 MTs of Yucatan Peninsula poultry may be available for export to the United States, depending on domestic consumption, a factor that is very difficult to gauge or predict. Based on these figures, the amount of breast meat cuts available for export to the United States ranges from roughly 5,786 to 16,875 MTs.²

¹ "Outlook for Mexican Poultry Industry and U.S.-Mexican Poultry Trade," Milton Madison and

David Harvey. USDA/ERS Livestock, Dairy, and Poultry Report, July 17, 1998, LDP-52.

² A 42-ounce processed broiler carcass is comprised of 12.5 to 14 ounces of breast meat, or roughly 32 percent breast meat.

TABLE 2.—ESTIMATED YUCANTAN PENINSULA POULTRY AND POULTRY PRODUCTS AVAILABLE FOR EXPORT TO THE UNITED STATES (IN MTs)

Potential Exports	High estimate	Low estimate
Total	100,000	100,000
Acceptable for U.S. import	70,000	60,000
Acceptable for U.S. import and available for export (not consumed domestically)	52,500	18,000
Estimated breast meat available for export to U.S.	16,875	5,786

Source: Centro de Estadística Agropecuaria/SAGARPA statistics provided by Leland Southard of USDA/ERS.

These amounts make up a minuscule share of the U.S. market. The United States is the world's largest producer and exporter of poultry meat. In 1999, U.S. poultry meat production totaled 35.3 billion pounds (159,090,909 MTs), of which 83 percent was broiler meat, 15 percent was turkey meat, and 2 percent was other chicken meat. The total farm value of U.S. poultry production in 1999 was \$22.4 billion. Broiler production accounted for the majority of the value at \$15.1 billion,

followed by eggs at \$4.3 billion, turkey at \$2.8 billion, and other chicken at \$68 million. The high estimate of 52,500 MTs of Yucatan Peninsula poultry and poultry parts available for export to the United States translates to 0.033 percent of U.S. poultry production based on the 1999 figures. The low estimate of 18,000 MTs available for export equals 0.0113 percent of 1999 U.S. production. The percentages for estimated breast meat exports, of course, are even smaller.

The Regulatory Flexibility Act requires that agencies specifically consider the economic impact of their rules on small entities. Among the small entities potentially affected by this rule change are U.S. producers of poultry and poultry products, U.S. freight forwarders, and U.S. trucking and shipping firms. All of these categories are comprised primarily of small entities. Table 3 provides a breakdown.

TABLE 3.—NUMBER AND TYPE OF SMALL BUSINESSES POTENTIALLY AFFECTED BY PROPOSED RULE

Type of business	Total U.S. entities	Small entities
Local and long distance U.S. trucking firms (refrigerated)	13,815	13,529
U.S. freight forwarders	5,771	5,674
Deep sea freight transport	431	273
Poultry farms	63,246	53,530

The U.S. poultry industry is dominated by contract growing arrangements. A small number of very large, vertically integrated poultry companies own most poultry in the United States. The poultry are raised to a marketable size by farmers under contract arrangements. The vertically integrated companies do not qualify as small entities under the Small Business Administration's standard for small poultry enterprises—no more than \$750,000 in annual revenues. Most contract poultry growers do qualify as small entities, however.³ The 1997 Census of Agriculture (the most recent data on the composition of poultry industry by size) reported a total of 63,246 farms in the United States that raised poultry or poultry products, producing poultry and poultry products valued at over \$22 billion. According to Census of Agriculture data, approximately 53,530 or 85 percent of

the farms raising poultry were “small” farms in 1997.⁴

In theory, imported Yucatan poultry will increase the available supply of poultry in the United States, increase competition, and reduce prices. Such a development, while benefitting U.S. consumers, will negatively affect net revenues of U.S. producers. Due to the relatively small tonnage of poultry and poultry products expected to be exported from the Yucatan Peninsula to the United States, however, this rule is unlikely to have a measurable effect on U.S. poultry and poultry product supplies, poultry prices, or poultry producer revenues.

The other affected small entities—U.S. freight forwarding, trucking, or transport firms that have the capacity to transport Mexican poultry from U.S. land border ports or U.S. maritime ports—may benefit from increased economic activity as a result of this rulemaking. As is the case with poultry producers, however, these effects are likely to be very small due to the limited

amount of poultry and poultry products expected to be exported to the United States from the Yucatan Peninsula States.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This final rule contains an information collection requirement that was not included in the proposed rule. Specifically, this final rule adds an additional 50 burden hours for a certification that will have to be completed by Federal animal health authorities in Mexico to ensure that,

³ <http://www.sba.gov>, NAICS Code 112320, poultry production.

⁴ 1997 Census of Agriculture—United States data, table 50, summary by market value of agricultural products sold.

prior to export to the United States, poultry and poultry products from Campeche, Quintana Roo, and Yucatan are not commingled with poultry and poultry products from END-affected regions. In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), we submitted this information collection requirement for approval to the Office of Management and Budget (OMB). OMB has approved the information collection for a period of 6 months under control number 0579-0228. We plan, in the near future, to request continuation of that approval for 3 years.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701-7772, and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

§ 94.6 [Amended]

■ 2. In § 94.6, paragraph (a)(2) is amended by adding the words "Mexico (States of Campeche, Quintana Roo, and Yucatan)," after the word "Luxembourg,".

■ 3. A new § 94.25 is added to read as follows:

§ 94.25 Restrictions on importation of live poultry, poultry meat, and other poultry products from specified regions.

The Mexican States of Campeche, Quintana Roo, and Yucatan, which are declared in § 94.6(a)(2) to be free of exotic Newcastle disease (END), supplement their meat supply by the importation of fresh (chilled or frozen) poultry meat from regions designated in § 94.6(a) as regions where END is considered to exist, have a common land border with regions where END is considered to exist, or import live poultry from regions where END is considered to exist under conditions less restrictive than would be acceptable for importation into the United States. Thus, even though the Department has declared such regions to be free of END, live poultry originating in such free regions may be commingled with live poultry originating in an END-affected region and the meat and other animal products produced in such free regions may be commingled with the fresh (chilled or frozen) meat of animals from an END-affected region, resulting in an undue risk of introducing END into the United States. Therefore, live poultry, poultry meat and other poultry products, and ship stores, airplane meals, and baggage containing such meat or animal products originating in the free regions listed in this section may not be imported into the United States unless the following requirements, in addition to all other applicable requirements of part 93 of this chapter and of chapter III of this title, are met:

(a) *Additional certification.* Live poultry, poultry meat, and other poultry products from any region designated in this section must be accompanied by an additional certification by a full-time salaried veterinary officer of the Government of Mexico. Upon arrival of the live poultry, poultry meat, or other poultry product in the United States, the certification must be presented to an authorized inspector at the port of arrival.

(b) *Live poultry.* The certification accompanying live poultry must identify the exporting region of the poultry as a region designated in § 94.6 as free of END at the time the poultry were in the region and must state that:

(1) The poultry have not been in contact with poultry or poultry products from any region where END is considered to exist;

(2) The poultry have not lived in a region where END is considered to exist; and

(3) The poultry have not transited through a region where END is considered to exist unless moved

directly through the region in a sealed means of conveyance with the seal intact upon arrival at the point of destination.

(c) *Poultry meat or other poultry products.* The certification accompanying poultry meat or other poultry products must state that:

(1) The poultry meat or other poultry products are derived from poultry that meet all requirements of this section and that have been slaughtered in a region designated in § 94.6 as free of END at a federally inspected slaughter plant that is under the direct supervision of a full-time salaried veterinarian of the Government of Mexico and that is approved to export poultry meat and other poultry products to the United States in accordance with § 381.196 of this title;

(2) The poultry meat or other poultry products have not been in contact with poultry meat or other poultry products from any region where END is considered to exist;

(3) The poultry meat or other poultry products have not transited through a region where END is considered to exist unless moved directly through the region in a sealed means of conveyance with the seal intact upon arrival at the point of destination; and

(4) If processed, the poultry meat or other poultry products were processed in a region designated in § 94.6 as free of END in a federally inspected processing plant that is under the direct supervision of a full-time salaried veterinarian of the Government of Mexico.

(Approved by the Office of Management and Budget under control number 0579-0228)

Done in Washington, DC, this 21st day of January, 2004.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04-1735 Filed 1-23-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. 97N-484R]

Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing

AGENCY: Food and Drug Administration, HHS.