H. Humphrey Building, whether personal or for the purpose of presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for the purpose of presentation.

Individuals requiring sign language interpretation or other special accommodation must contact the DFO via the contact information specified in the **FOR FUTHER INFORMATION CONTACT** section of this notice by the date listed in the **DATES** section of this notice.

Authority: (Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, section 10(a)).)

Dated: April 10, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–7382 Filed 4–26–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0018]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Form Food and Drug Administration 3356; Eligibility Determination for Donors; and Current Good Tissue Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 29, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974. All comments should be identified with the OMB control number 0910–0543. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Form Food and Drug Administration 3356; Eligibility Determination for Donors; and Current Good Tissue Practice (OMB Control Number 0910–0543)—Extension

Under section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or possessions or from foreign countries into the States. As derivatives of the human body, all human cells, tissues, and cellular and tissue-based products (HCT/Ps) pose some risk of carrying pathogens that could potentially infect recipients or handlers. FDA has issued regulations related to HCT/Ps involving establishment registration and listing using Form FDA 3356; eligibility determination for donors; and current good tissue practice (CGTP).

Establishment Registration and Listing; Form FDA 3356

The regulations in part 1271 (21 CFR part 1271) require domestic and foreign establishments that recover, process, store, label, package, or distribute any HCT/Ps, or that perform screening or testing of the cell or tissue donor to register with FDA (§ 1271.10(b)(1)) and submit a list of each HCT/P manufactured (§ 1271.10(b)(2)).Section 1271.21(a) requires the initial establishment registration, and § 1271.25(a) and (b) identifies the required initial registration and HCT/P listing information. Section 1271.21(b) requires an annual update of the establishment registration. Section 1271.21(c)(ii) requires establishments to submit HCT/P listing updates when an HCT/P is changed as described in § 1271.25(c). Section 1271.25(c) identifies the required HCT/P listing update information. Section 1271.26 requires establishments to submit an amendment if ownership or location of the establishment changes. FDA requires the use of a registration and listing form (Form FDA 3356: Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products to submit the required information (§§ 1271.10, 1271.21, 1271.25, and 1271.26)). To further facilitate the ease and speed of submissions, electronic submission is accepted (*http://www.fda.gov/cber/tissue/tisreg.htm*).

Eligibility Determination for Donors

FDA requires HCT/P establishments described in § 1271.1(b) to screen and test the donors of cells and tissue used in those products for risk factors for and clinical evidence of relevant communicable diseases agents and diseases. The documented determination of a donor's eligibility is made by a responsible person and is based on the results of required donor screening, which includes a donor medical history interview (defined in § 1271.3(n)), and testing (§ 1271.50(a)). HCT/P establishments are permitted to ship an HCT/P only if it is accompanied by documentation of the donor-eligibility determination (§ 1271.55(a)). This requirement applies to an HCT/P from a donor determined to be eligible as well as to a product from a donor who is determined to be ineligible and made available for use under certain provisions. The accompanying documentation must contain a summary of records used to determine donor eligibility, and a statement whether, based on the results of the screening and testing of the donor, that the donor is determined to be eligible or ineligible. Records used in determining the eligibility of a donor, i.e., results and interpretations of screening and testing, the donor eligibility determination, the name and address of the testing laboratory or laboratories, and the name of the responsible person who made the determination and the date, must be maintained (§ 1271.55(d)(1)). If any information on the donor is not in English, the HCT/P establishment must retain the original record and the statement of authenticity from the translator (§ 1271.55(d)(2)). HCT/P establishments must retain the records pertaining to HCT/Ps at least 10 years after the date of administration, distribution, disposition, or expiration, whichever is latest (§ 1271.55(d)(4)).

When a product is shipped in quarantine, before completion of screening and testing, the HCT/P establishment must provide the donor identification, a statement that the donor-eligibility determination is not completed and that the product is not to

be used until eligibility determination is completed (§ 1271.60(c)). With the use of a product from an incompletely tested donor, the results of any completed donor screening and testing, and a list of any required screening and testing not yet completed must accompany the HCT/P (§ 1271.60(d)(2)). When using an HCT/P from an ineligible donor, documentation by the HCT/P establishment is required showing that the recipient's physician received notification of the screening and testing results (§§ 1271.60(d)(3) and 1271.65(b)(3)). An HCT/P establishment is also required to establish and maintain procedures for all steps that are performed in determining eligibility (§ 1271.47(a)), including the use of a product from a donor testing positive for cytomegalovirus (§ 1271.85(b)(2)). The HCT/P establishment must record any departure from the procedures (§ 1271.47(d)).

Current Good Tissue Practice

FDA requires certain HCT/P establishments to follow CGTPs. Section 1271.155(a) permits the submission of a request for FDA approval of an exemption or an alternative from any requirement in subpart C or D of part 1271. Section 1271.290(c) requires the establishment to affix a distinct identification code to each HCT/P relating the HCT/P to the donor and all records pertaining to the HCT/P. Whenever an establishment initially distributes an HCT/P to a consignee, § 1271.290(f) requires the establishment to inform the consignee, in writing, of the product tracking requirements and the methods the establishment uses to fulfill the requirements. Non-reproductive HCT/P establishments described in § 1271.10 are required under § 1271.350(a)(1), and (b)(1) and (b)(2) to investigate and report to FDA adverse reactions (defined in § 1271.3(y)) and HCT/P deviations (defined in § 1271.3(dd)). Section 1271.370(b) and (c) requires establishments to include specific information either on the HCT/P label or in the package insert.

The standard operating procedures (SOP) provisions under part 1271 include the following: (1) Section 1271.160(b)(2) (receiving, investigation, evaluating, and documenting information relating to core CGTP requirements received from other sources and for sharing information with consignees and other establishments); (2) section 1271.180(a) (to meet core CGTP requirements for all steps performed in the manufacture of HCT/Ps); (3) section 1271.190(d)(1) (facility cleaning and sanitization); (4) section 1271.200(b) (cleaning, sanitizing, and maintenance of equipment); (5) section 1271.200(c) (calibration of equipment); (6) section 1271.230(a) (verification or validation of changes to a process); (7) section 1271.250(a) (controls for labeling HCT/Ps); (8) section 1271.265(e) (receipt, pre-distribution shipment, availability for distribution, and packaging and shipping of HCT/Ps); (9) section 1271.265(f) (suitable for return to inventory); (10) section 1271.270(b) (records management system); (11) section 1271.290(b)(1) (system of HCT/P tracking); and (12) section 1271.320(a) (review, evaluation, and documentation of all complaints).

Section 1271.155(f) requires an establishment operating under the terms of an exemption or alternative to maintain documentation of the terms and date of FDA approval. Section 1271.160(b)(3) requires documentation of corrective actions taken as a result of an audit of the quality program. Section 1271.160(b)(6) requires documentation of HCT/P deviations. Section 1271.160(d) requires documentation of computer validation or verification activities and results when computers are used to comply with the core CGTP requirements for its intended use. Section 1271.190(d)(2) requires documentation of all significant facility cleaning and sanitation. Section 1271.195(d) requires documentation of environmental control and monitoring activities. Section 1271.200(e) requires documentation of all equipment maintenance, cleaning, sanitizing, calibration, and other activities. Section 1271.210(d) requires documentation of the receipt, verification, and use of each supply or reagent. Section 1271.230(a) requires documentation of validation activities when the results of a process cannot be fully verified by subsequent inspection and tests. Section 1271.230(c) requires documentation of the review and evaluation of a process and revalidation of the process, if necessary, when any changes to a validated process occur. Section 1271.260(d) and (e) requires documentation of any corrective action taken when acceptable storage conditions are not met and documentation of the storage temperature of HCT/Ps.

Section 1271.265(c)(1) requires documentation that all release criteria are met before distribution of an HCT/P. Section 1271.265(c)(3) requires documentation of any departure from a procedure at the time of occurrence. Section 1271.265(e) requires documentation of the receipt, pre-distribution shipment, distribution, and packaging and shipping of HCT/Ps. Section 1271.270(a) requires documentation of each step in manufacturing required in part 1271, subparts C and D. Section 1271.270(e) requires documentation of the name and address, and a list of responsibilities of any establishment that performs a manufacturing step for the establishment. Section 1271.290(d) and (e) requires documentation of a method for the recording and disposition of each HCT/P as part of its tracking system. Section 1271.320(b) requires an establishment to maintain a record of each complaint that it receives, including a review and evaluation.

Respondents to this information collection are establishments that recover, process, store, label, package or distribute any HCT/P, or perform donor screening or testing. The estimates provided below are based on information from FDA's database system and trade organizations for 2006. The hours per response and hours per record are based on data provided by the Eastern Research Group, or FDA experience with similar recordkeeping or reporting requirements.

There are an estimated 2,017 HCT/P (conventional tissue, eye tissue, peripheral blood stem cell, stem cell products from cord blood, reproductive tissue, and sperm banks) establishments, including 481 manufacturers of HCT/P products regulated under the Federal Food, Drug, and Cosmetic Act and section 351 of the PHS Act that have registered and listed with FDA. In addition, we estimate that 241 new establishments have registered with FDA (§§ 1271.10(b)(1) and (b)(2) and 1271.25(a) and (b)). There are an estimated 3,289 listing updates (§§ 1271.10(b)(2), 1271.21(c)(2)(ii) and 1271.25(c)) and 500 location/ownership amendments (§ 1271.26).

Under § 1271.55(a), an estimated 1,677,105 HCT/Ps (approximately 1,500,000 conventional tissues, 44,186 eye tissues, 7,919 hematopoetic stem cells/progenitor cells (total of 1,552,105 non-reproductive cells and tissues), and 125,000 reproductive cells and tissues) are distributed per year by an estimated 1,536 establishments (2,017 - 481 establishments with approved applications). Under § 1271.60(c), FDA estimates that 1,200 establishments shipped an estimated 250,000 HCT/P under quarantine, and that an estimated 8 establishments requested an exemption from or alternative to any requirement under part 1271, subpart C or D, specifically under § 1271.155(a).

Under §§ 1271.290(c) and 1271.370(b) and (c), the estimated 1,449 non-reproductive HCT/P establishments

label each of their 1,552,105 HCT/Ps with certain information. These establishments are also required to inform their consignees in writing of the requirements for tracking and of their established tracking system under § 1271.290(f).

FDA estimates 42 HCT/P establishments submitted 67 adverse reaction reports involving communicable disease (§ 1271.350(a)(1)), and 81 establishments submitted 144 deviation reports relating to the core CGTP requirements (§ 1271.350(b)(1)).

FDA estimates that 241 new establishments will create SOPs, and that 2,017 establishments will review and revise existing SOPs annually.

FDA estimates that 1,009 HCT/P establishments (2,017 x 50% = 1,009) and 725 non-reproductive HCT/P establishments (1,449 x 50% = 725) record and justify a departure from the procedures (§ 1271.47(d) and § 1271.265(c)(3)).

Under § 1271.50(a), HCT/P establishments are required to have a documented medical history interview about the donor's medical history and relevant social behavior as part of the donor's relevant medical records for each of the estimated 77,944 donors (approximately 23,295 conventional tissue donors, 42,649 eye tissue donors, 7,000 peripheral and cord blood stem cell donors (72,944 non-reproductive cells and tissue donors), and 5,000 reproductive cell and tissue donors).

FDA estimates that 605 HCT/P establishments (2,017 x 30% = 605) document an urgent medical need of the product to notify the physician using the HCT/P (§§ 1271.60(d)(3) and 1271.65(b)(3)).FDA also estimates that 1614 HCT/P establishments (2,017 x 80% = 1,614) have to maintain records for an average of 2 contract establishments to perform their manufacturing process (§ 1271.270(e)) and 1,009 HCT/P establishments maintain an average of 5 complaint records annually (§ 1271.320(b)).

In some cases, the estimated burden may appear to be lower or higher than the burden experienced by individual establishments. The estimated burden in these charts is an estimated average burden, taking into account the range of impact each regulation may have.

In the **Federal Register** of January 26, 2007 (72 FR 3858), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1271.10(b)(1) and 1271.21(b)(2)[2]	2,017	1	2,017	0.5	1,009
1271.21(a), and 1271.25(a) and (b)[2]	241	1	241	0.75	181
1271.10(b)(2), 1271.21(c)(ii) and 1271.25(c)[2]	3,289	1	3,289	0.5	1,644
1271.26[2]	500	1	500	0.25	125
1271.55(a)	1,536	1,091.87	1,677,105	0.5	838,553
1271.60(c) and (d)(2)	1,200	208.33	250,000	0.5	125,000
1271.155(a)	8	1	8	3	24
1271.290(c)	1,449	1,071.16	1,552,105	0.08	124,168.33
1271.290(f)	1,449	1	1,449	1	1,449
1271.350(a)(1)	42	1.60	67	1	67
1271.350(b)(1) and (b)(2)	81	1.78	144	1	144
1271.370(b) and (c)	1,449	1,071.16	1,552,105	0.25	388,026.25
Total					1,480,390

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Using Form FDA 3356.

FDA estimates the burden of this collection of information as follows:

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record	Total Hours
New SOPs[2]	241	1	241	48	11,568
SOP Update[2]	2,017	1	2,017	24	48,408
1271.47(d)	1,009	1	1,009	1	1,009

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record	Total Hours
1271.50(a)	2,017	38.64	77,944	5	389,720
1271.55(d)(1)	2,017	38.64	77,944	1	77,944
1271.55(d)(2)	2,017	1	2,017	1	2,017
1271.55(d)(4)	2,017	1	2,017	120	242,040
1271.60(d)(3) and 1271.65(b)(3)	605	1	605	2	1,210
1271.155(f)	8	1	8	0.25	2
1271.160(b)(3) and (b)(6)	1,449	12	17,388	1	17,388
1271.160(d)	1,449	12	17,388	1	17,388
1271.190(d)(2)	1,449	12	17,388	1	17,388
1271.195(d)	1,449	12	17,388	1	17,388
1271.200(e)	1,449	12	17,388	1	17,388
1271.210(d)	1,449	12	17,388	1	17,388
1271.230(a)	1,449	12	17,388	1	17,388
1271.230(c)	1,449	1	1,449	1	1,449
1271.260(d)	1,449	12	17,388	0.25	4,347
1271.260(e)	1,449	365	528,885	0.08	42,310.8
1271.265(c)(1)	1,449	1,071.16	1,552,105	0.08	124,168.33
1271.265(c)(3)	725	1	725	1	725
1271.265(e)	1,449	1,071.16	1,552,105	0.08	124,168.33
1271.270(a)	1,449	1,071.16	1,552,105	0.25	388,026.25
1271.270(e)	1,614	2	3,228	0.5	1,614
1271.290(d) and (e)	1,449	50.34	72,944	0.25	18,236
1271.320(b)	1,009	5	5,045	1	5,045
Total					1,605,723.7

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Sections 1271.47(a), 1271.85(b)(2), 1271.160(b)(2), 1271.180(a), 1271.190(d)(1), 1271.200(b) and (c), 1271.230(a), 1271.250(a), 1271.265(e), and 1271.320(a).

Dated: April 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–8038 Filed 4–26–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007P–0149]

Canned Pacific Salmon Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Peter Pan Seafoods, Inc., to market test canned Pacific salmon that deviates from the U.S. standard of identity for canned Pacific salmon. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product and assess commercial feasibility.

DATES: This permit is effective for 15 months, beginning on the date the permit holder introduces or causes the introduction of the test product into interstate commerce, but not later than July 27, 2007.

FOR FURTHER INFORMATION CONTACT: Ritu Nalubola, Center for Food Safety and