TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.3(f)(1)	0.1	1	0.1	0	0		
900.4(g)	5	1	5	1	5		
900.12(a)(1)(i)(B)(*2*)	87	1	87	8	696		
900.12(a)(4)	8,681	4	34,724	1	34,724		
900.12(c)(4)	8,681	1	8,681	1	8,681	$28,000	
900.12(e)(13)	8,681	52	451,412	.083333	37,618		
900.12(f)	8,681	1	8,681	16	138,896		
900.12(h)(2)	8,681	2	17,362	1	17,362		
900.22(a)	5	1	5	1	5		
900.22(d)	5	1	5	1	5		
900.22(e)	5	1	5	1	5		
900.22(f)	3	1	3	1	3		
900.22(g)	5	1	5	1	5		$50
900.25(b)	5	1	5	1	5		
Total					238,010	$28,000	$50

The following sections of title 21 of the Code of Federal Regulations (CFR) were not included in the previously mentioned burden tables because they were considered usual and customary practice and were part of the standard of care prior to the implementation of the regulations. Therefore, they resulted in no additional reporting or recordkeeping burden: 21 CFR 900.12(c)(1) and (c)(3) and 21 CFR 900.3(f)(1).

Section 900.3(c) was not included in the previously mentioned burden tables because all four existing accreditation bodies are approved until late in 2013; so, no applicants will reapply during the requested information collection period. Section 900.24(c) was also not included in the previously mentioned burden tables because if a certifying state had its approval withdrawn, FDA would take over certifying authority for the affected facilities. Because FDA already has all the certifying state's electronic records, there wouldn't be an additional reporting burden.

Dated: March 8, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–5230 Filed 3–11–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0101]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Form FDA 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements for FDA regulations related to human cells, tissues, and cellular and tissue-based products (HCT/Ps) involving establishment registration and listing using Form FDA 3356; eligibility determination for donors; and current good tissue practice (CGTP).

DATES: Submit written or electronic comments on the collection of information by May 10, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c)

and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Form FDA 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 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 CGTP.

A. 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 an HCT/P described in § 1271.10(a), 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)). Section 1271.21(a) requires an establishment to follow certain procedures for initial registration and listing of HCT/Ps, and § 1271.25(a) and (b) identifies the required initial registration and HCT/P listing information. Section 1271.21(b), in brief, 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 (HCT/Ps)) 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/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/default.htm*).

B. Eligibility Determination for Donors

In brief, FDA requires certain HCT/P establishments described in § 1271.1(b) to determine donor eligibility based on donor screening and testing for relevant communicable diseases agents and diseases, except as provided under § 1271.90. The documented determination of a donor's eligibility is made by a responsible person defined in § 1271.3(t) 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)). Certain records must accompany an HCT/P once the donor-eligibility determination has been made (§ 1271.55(a)). This requirement applies both to an HCT/P from a donor who is determined to be eligible as well as to an HCT/P from a donor who is determined to be ineligible or where the donor-eligibility determination is not complete if there is a documented urgent medical need (§ 1271.60). Once the donor-eligibility determination has been made, the HCT/P must be accompanied by a summary of records used to make the donor-eligibility determination (§ 1271.55(b)) and a statement whether, based on the results of the screening and testing, the donor is determined to be eligible or ineligible (§ 1271.55(a)(2)).

Records used in determining the eligibility of a donor, i.e., results and interpretations of testing for relevant communicable disease agents, the donor-eligibility determination, the name and address of the testing laboratory or laboratories, and the name of the responsible person (defined in § 1271.3(t)) who made the donor-eligibility determination and the date of the determination, must be maintained (§ 1271.55(d)(1)). If any information on the donor is not in English, the original record must be retained and translated to English and accompanied by a 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 as defined in § 1271.3(q), before completion of screening and testing, the HCT/P must be accompanied by records identifying the donor; stating that the donor-eligibility determination has not been completed; and stating that the product must not be used until the donor-eligibility determination has been completed (§ 1271.60(c)). When an HCT/P is used in cases of documented urgent medical need, the results of any completed donor screening and testing, and a list of any required screening and testing not yet completed also must accompany the HCT/P (§ 1271.60(d)(2)). When an HCT/P is used in cases of urgent medical need or from a donor who has been determined to be ineligible (as permitted under § 1271.65), documentation by the HCT/P establishment is required showing that the recipient's physician received notification that the testing and screening were not complete (in cases of urgent medical need), and upon the completion of the donor-eligibility determination, of the results of the determination (§ 1271.60(d)(3) and (d)(4) 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 reactive for cytomegalovirus (§ 1271.85(b)(2)). The HCT/P establishment must record any departure from the procedures (§ 1271.47(d)).

C. Current Good Tissue Practice (CGTP)

FDA requires certain HCT/P establishments to follow CGTP

(§ 1271.1(b)). Section 1271.155(a) permits the submission of a request for FDA approval of an exemption from or alternative to any requirement in subpart C or D of part 1271. Section 1271.290(c) requires such establishments to affix a distinct identification code to each HCT/P that it manufactures that relates the HCT/P to the donor and to all records pertaining to the HCT/P. Whenever an establishment 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 (a)(3) to investigate and report to FDA adverse reactions (defined in § 1271.3(y)) using Form FDA–3500A (§ 1271.350(a)(2)). Form FDA–3500A is approved under OMB Control No. 0910–0291. Section 1271.370(b) and (c) requires establishments to include specific information either on the HCT/P label or with the HCT/P.

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, including complaints, and for sharing information with consignees and other establishments); (2) § 1271.180(a) (to meet core CGTP requirements for all steps performed in the manufacture of HCT/Ps); (3) § 1271.190(d)(1) (facility cleaning and sanitization); (4) § 1271.200(b) (cleaning, sanitizing, and maintenance of equipment); (5) § 1271.200(c) (calibration of equipment); (6) § 1271.230(a) and (c) (validation of changes to a process); (7) § 1271.250(a) (controls for labeling HCT/Ps); (8) § 1271.265(e) (receipt, predistribution shipment, availability for distribution, and packaging and shipping of HCT/Ps); (9) § 1271.265(f) (suitable for return to inventory); (10) § 1271.270(b) (records management system); (11) § 1271.290(b)(1) (system of HCT/P tracking); and (12) § 1271.320(a) (review, evaluation, and documentation of complaints (as defined in § 1271.3(aa))).

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 appropriate 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 facility cleaning and sanitation activities performed to prevent contamination of HCT/Ps. Section 1271.195(d) requires documentation of environmental control and monitoring activities. Section 1271.200(e) requires documentation of 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 proper storage conditions are not met and documentation of storage temperatures for HCT/Ps. Section 1271.265(c)(1) requires documentation that release criteria have been met before distribution of an HCT/P. Section 1271.265(c)(3) requires documentation of any departure from a procedure at the time of its occurrence. Section 1271.265(e) requires documentation of the receipt, predistribution 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 an establishment. Sections 1271.290(d) and (e) require documentation of a method for recording the distinct identification code and type of each HCT/P distributed to a consignee to enable tracking from the consignee to the donor and to enable tracking from the donor to the consignee or final disposition. Section 1271.320(b) requires an establishment to maintain a record of each complaint that it receives, that contains relevant information for proper 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 the most recent available information from FDA's database system and trade organizations. 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 2,281 HCT/P establishments (conventional tissue, eye tissue, peripheral blood stem cell, stem cell products from cord blood, reproductive tissue, and sperm banks), including 692 manufacturers of HCT/P products regulated under the Federal Food, Drug, and Cosmetics Act and section 351 of the PHS Act (42 U.S.C. 262), that have registered and listed with FDA. In addition, we estimate that 251 new establishments have registered with FDA (§ 1271.10(b)(1) and (b)(2) and § 1271.25(a) and (b)). There are an estimated 2,230 listing updates (§§ 1271.10(b)(2), 1271.21(c)(ii), and 1271.25(c)) and 565 location/ownership amendments (§ 1271.26).

Under § 1271.55(a), an estimated total of 2,167,396 HCT/Ps (which include conventional tissues, eye tissues, hematopoetic stem cells/progenitor cells, and reproductive cells and tissues) and an estimated total of 2,026,024 non-reproductive cells and tissues (total HCT/Ps minus reproductive cells and tissues) are distributed per year by an estimated 1,589 establishments (2,281 - 692 = 1,589 establishments with approved applications).

Under § 1271.60(c) and (d)(2), FDA estimates that 1,375 establishments shipped an estimated 286,000 HCT/Ps under quarantine, and that an estimated 18 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), an estimated 1,694 non-reproductive HCT/P establishments label each of their 2,026,024 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 38 HCT/P establishments submitted 76 adverse reaction reports involving a communicable disease (§ 1271.350(a)(1)).

FDA estimates that 251 new establishments will create SOPs, and that 2,281 establishments will review and revise existing SOPs annually.

FDA estimates that 1,141 HCT/P establishments (2,281 x 50% = 1,141)

and 847 non-reproductive HCT/P establishments (1,694 x 50% = 847) 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 total of 91,240 donors (which include conventional tissue donors, eye tissue donors, peripheral and cord blood stem cell donors, and reproductive cell and tissue donors), and the estimated total of 86,394 non-reproductive cells and tissue donors (total donors minus reproductive cell and tissue donors).

FDA estimates that 684 HCT/P establishments (2,281 x 30% = 684) document an urgent medical need for an HCT/P and notify the physician using the HCT/P (§ 1271.60(d)(3) and (d)(4) and § 1271.65(b)(3)(iii)).

FDA also estimates that 1,824 HCT/P establishments (2,281 x 80% = 1,824) have to maintain records for an average of 2 contract establishments that perform a manufacturing process step for them (§ 1271.270(e)) and 1,141 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.

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

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]	2,281	1	2,281	.5	1,141
1271.10(b)(1) and (b)(2), 1271.21(a), and 1271.25(a) and (b)[2]	251	1	251	.75	188
1271.10(b)(2), 1271.21(c)(2)(ii), and 1271.25(c)[2]	2,230	1	2,230	.5	1,115
1271.26[2]	565	1	565	.25	141
1271.55(a)	1,589	1,364	2,167,396	.5	1,083,698
1271.60(c) and (d)(2)	1,375	208	286,000	.5	143,000
1271.155(a)	18	1	18	3	54
1271.290(c)	1,694	1,196	2,026,024	.083	168,835
1271.290(f)	1,694	1	1,694	1	1,694
1271.350(a)(1) and (a)(3)	38	2	76	1	76
1271.370(b) and (c)	1,694	1,196	2,026,024	.25	506,506
Total					1,906,448

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
New SOPs[2]	251	1	251	48	12,048
SOP Update[2]	2,281	1	2,281	24	54,744
1271.47(d)	1,141	1	1,141	1	1,141
1271.50(a)	2,281	40	91,240	5	456,200
1271.55(d)(1)	2,281	40	91,240	1	91,240
1271.55(d)(2)	2,281	1	2,281	1	2,281
1271.55(d)(4)	2,281	1	2,281	120	273,720
1271.60(d)(3) and (d)(4), and 1271.65(b)(3)(iii)	684	1	684	2	1,368
1271.155(f)	18	1	18	.25	5

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

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1271.160(b)(3) and (b)(6)	1,694	12	20,328	1	20,328
1271.160(d)	1,694	12	20,328	1	20,328
1271.190(d)(2)	1,694	12	20,328	1	20,328
1271.195(d)	1,694	12	20,328	1	20,328
1271.200(e)	1,694	12	20,328	1	20,328
1271.210(d)	1,694	12	20,328	1	20,328
1271.230(a)	1,694	12	20,328	1	20,328
1271.230(c)	1,694	1	1,694	1	1,694
1271.260(d)	1,694	12	20,328	.25	5,082
1271.260(e)	1,694	365	618,310	.083	51,526
1271.265(c)(1)	1,694	1,196	2,026,024	.083	168,835
1271.265(c)(3)	847	1	847	1	847
1271.265(e)	1,694	1,196	2,026,024	.083	168,835
1271.270(a)	1,694	1,196	2,026,024	.25	506,506
1271.270(e)	1,824	2	3,648	.5	1,824
1271.290(d) and (e)	1,694	51	86,394	.25	21,599
1271.320(b)	1,141	5	5,705	1	5,705
Total					1,967,496

[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) and (d)(1), 1271.180(a), 1271.190(d)(1), 1271.200(b), 1271.200(c), 1271.230(a), 1271.250(a), and 1271.265(e).

Dated: March 8, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–5229 Filed 3–10–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0109]

Determination That PRO–BANTHINE (Propantheline Bromide) Tablets and 14 Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the 15 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Olivia Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, a drug is withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).