TABLE 1—SERVICE INFORMATION—Continued

Airbus service information	Revision	Date
Service Bulletin A340–53–4165	Original	September 19, 2007.

Material Incorporated by Reference

(i) You must use the service information specified in Table 2 of this AD to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 33 33; Internet *http://www.airbus.com.*

(3) You may review copies at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

TABLE 2—MATERIAL INCORPORATED BY REFERENCE

Airbus service information	Revision	Date
Mandatory Service Bulletin A330–53–3160	Original	July 9, 2007.
Mandatory Service Bulletin A330–53–3168	01	February 15, 2008.
Mandatory Service Bulletin A340–53–4172	Original	July 10, 2007.
Mandatory Service Bulletin A340–53–4174	01	February 15, 2008.
Service Bulletin A330–53–3159	Original	September 19, 2007.
Service Bulletin A340–53–4165	Original	September 19, 2007.

Issued in Renton, Washington, on October 20, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–25787 Filed 11–10–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

[Docket No. FDA–2008–N–0561]

Maximum Civil Money Penalty Amounts and Compliance With the Federal Civil Penalties Inflation Adjustment Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a new regulation to adjust for inflation the maximum civil money penalty amounts for the various civil money penalty authorities within our jurisdiction. We are taking this action to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA), as amended. The last adjustment was published in the **Federal Register** of July 20, 2004 (69 FR 43299), and the FCPIAA requires Federal agencies to adjust their civil money penalties at least once every 4 years. This rule does not adjust the civil money provisions enacted by the Food and Drug Administration Amendments Act of 2007 (FDAAA). We are using direct final rulemaking for this action because the agency expects that there will be no significant adverse comment on the rule. In the proposed rule section of this issue of the **Federal Register**, we are concurrently proposing and soliciting comments on this rule. If significant adverse comments are received, we will withdraw this final rule and address the comments in a subsequent final rule. FDA will not provide additional opportunity for comment.

DATES: This rule is effective March 27, 2009, without further notice, unless FDA receives significant adverse comment by January 26, 2009. If we receive no timely significant adverse comments, we will publish a document in the **Federal Register** before February 25, 2009, confirming the effective date of the direct final rule. If we receive any timely significant adverse comments, we will publish a document in the **Federal Register** withdrawing this direct final rule before March 27, 2009.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2008–N–0561, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No. FDA–2008–N–0561 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments

regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Erik Mettler, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

In general, the FCPIAA (28 U.S.C. 2461 note, as amended by the Debt Collection Improvement Act of 1996 (31 U.S.C. 3701)) requires Federal agencies to issue regulations to adjust for inflation each civil monetary penalty provided by law within their jurisdiction. The FCPIAA directs agencies to adjust the civil monetary penalties by October 23, 1996, and to make additional adjustments at least once every 4 years thereafter. The adjustments are based on changes in the cost of living, and the FCPIAA defines the cost of living adjustment as: ''* * * the percentage (if any) for each civil monetary penalty by which—(1) the Consumer Price Index for the month of June of the calendar year preceding the adjustment, exceeds (2) the Consumer Price Index for the month of June of the calendar year in which the amount of such civil monetary penalty was last set or adjusted pursuant to law''(28 U.S.C. 2461 note, section 5(b)).

The FCPIAA also prescribes a rounding method based on the size of the penalty after the calculated increase, but states that the first adjustment of a civil monetary penalty may not exceed 10 percent of the penalty.

The FCPIAA defines a civil monetary penalty as: ''any penalty, fine, or other sanction that—(A)(i) is for a specific monetary amount as provided by Federal law; or (ii) has a maximum amount provided for by Federal law; and (B) is assessed or enforced by an agency pursuant to Federal law; and (C) is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal Courts'' (28 U.S.C. 2461 note, section 3(2)).

Congress enacted the FCPIAA, in part, because it found that the impact of civil monetary penalties had been reduced by inflation and that reducing the impact of civil monetary penalties had weakened their deterrent effect.

In the **Federal Register** of July 20, 2004 (69 FR 43299), we published a final rule that identified 14 civil monetary penalties that fall within our jurisdiction and are subject to adjustments under the FCPIAA. The final rule amended our regulations governing civil money penalties hearings found at part 17 (21 CFR part 17) to establish a new § 17.2 entitled ''Maximum penalty amounts'' to show the maximum civil monetary penalty amounts that were adjusted under the FCPIAA. The final rule also revised § 17.1, which lists statutory provisions authorizing civil money penalties governed by the civil money penalty regulations as of August 28, 1995, updating the statutory citations.

FDA is publishing this rule as a direct final rule without prior proposal and comment because we view this as a noncontroversial amendment and anticipate no significant adverse comment. This rule incorporates requirements specifically set forth in the FCPIAA requiring FDA to issue a regulation implementing inflation adjustments for all its civil penalty provisions. These technical changes, required by law, do not substantively alter the existing regulatory framework, nor do they in any way affect the terms under which civil penalties are assessed by FDA. The formula for the amount of the penalty adjustment is prescribed by Congress in the FCPIAA, and these changes are not subject to the exercise of discretion by FDA. In addition, FDA has made conforming changes to the regulations, which have no substantive effect, to reflect the new penalties prescribed by Congress in FDAAA.

II. What Changes Did We Make?

We revised the list of statutory monetary penalties in § 17.1 to include the new penalties prescribed by the Federal Food, Drug, and Cosmetic Act, as amended by FDAAA in 2007. These new penalties have been added as new paragraphs (c) and (d). The table in § 17.2 has also been amended to include the new penalties, and the adjusted maximum penalty amounts for the pre-FDAAA penalties have been updated to account for the inflation between June 2004 (the year of the last adjustment) and June 2007 as prescribed by FCPIAA. The per violation amount for 21 U.S.C. 333(f)(1)(A), the per violation per person amount for 21 U.S.C. 360pp(b)(1), and the per violation amount for 42 U.S.C. 263b(h)(3) have not been adjusted because the rounding rules of FCPIAA prevent an inflation adjustment in these cases. The new FDAAA penalties have also not been adjusted because Congress only recently passed FDAAA on September 27, 2007. Finally, the ''Description of the Violation'' column in the table in § 17.2 has been removed, as it is unnecessary for purposes of merely showing the adjustment in penalty amounts.

III. What Does the Direct Final Rule Do?

In brief, the direct final rule:

- Revises § 17.1 to update the statutory citations regarding the new civil monetary penalties prescribed by FDAAA, and
- Revises the table in § 17.2 to include the new FDAAA penalties, and adjusts the pre-FDAAA maximum civil penalty amounts for inflation as prescribed by FCPIAA.

IV. Environmental Impact

We have determined under 21 CFR 25.30(a) and (h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act 1995

We conclude that the civil monetary penalties adjustments in this final rule are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The adjustments do not require disclosure of any information to FDA, third parties, or the public.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and

benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule simply adjusts the maximum amount of civil monetary penalties administered by FDA, and because the adjustment is required by the FCPIAA, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

List of Subjects in 21 CFR Part 17

Administrative practice and procedure, Penalties.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 17 is amended as follows:

PART 17—CIVIL MONEY PENALTIES HEARINGS

■ 1. The authority citation for 21 CFR part 17 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa–28; 5 U.S.C. 554, 555, 556, 557.

■ 2. Section 17.1 is amended by redesignating paragraphs (c) through (g) as paragraphs (e) through (i) and by adding new paragraphs (c) and (d) to read as follows:

§ 17.1 Scope.

* * * * *

(c) Section 303(f)(3) of the act authorizing civil money penalties for certain violations relating to the submission of certifications and/or clinical trial information to the clinical trial data bank and section 303(f)(4) of the act authorizing civil money penalties for certain violations of the act relating to postmarket studies, clinical trial requirements, and risk evaluation and mitigation strategies for drugs.

(d) Section 303(g)(1) of the act authorizing civil money penalties for certain violations of the act that relate to dissemination of direct-to-consumer advertisements for approved drugs or biological products.

* * * * *

■ 3. Section 17.2 is revised to read as follows:

§ 17.2 Maximum penalty amounts.

The following table shows maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under the act or the Public Health Service Act.

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS

U.S.C. Section	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment	Adjusted Maximum Penalty Amount (in dollars)
21 U.S.C.				
333(b)(2)(A)	55,000	For each of the first two violations in any 10-year period	2008	60,000
333(b)(2)(B)	1,100,000	For each violation after the second conviction in any 10-year period	2008	1,200,000
333(b)(3)	110,000	Per violation	2008	120,000
333(f)(1)(A)	16,500	Per violation	2008	16,500 (not adjusted)
333(f)(1)(A)	1,100,000	For the aggregate of violations	2008	1,200,000
333(f)(2)(A)	55,000	Per individual	2008	60,000
333(f)(2)(A)	275,000	Per ''any other person''	2008	300,000
333(f)(2)(A)	550,000	For all violations adjudicated in a single proceeding	2008	600,000

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—Continued

U.S.C. Section	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment	Adjusted Maximum Penalty Amount (in dollars)
333(f)(3)(A)	10,000	For all violations adjudicated in a single proceeding	2007	10,000 (not adjusted)
333(f)(3)(B)	10,000	For each day the violation is not corrected after a 30-day period following notification until the violation is corrected	2007	10,000 (not adjusted)
333(f)(4)(A)(i)	250,000	Per violation	2007	250,000 (not adjusted)
333(f)(4)(A)(i)	1,000,000	For all violations adjudicated in a single proceeding	2007	1,000,000 (not adjusted)
333(f)(4)(A)(ii)	250,000	For the first 30-day period (or any portion thereof) of continued violation following notification	2007	250,000 (not adjusted)
333(f)(4)(A)(ii)	1,000,000	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day period	2007	1,000,000 (not adjusted)
333(f)(4)(A)(ii)	10,000,000	For all violations adjudicated in a single proceeding	2007	10,000,000 (not adjusted)
333(g)(1)	250,000	For the first violation in any 3-year period	2007	250,000 (not adjusted)
333(g)(1)	500,000	For each subsequent violation in any 3-year period	2007	500,000 (not adjusted)
335b(a)	275,000	Per violation for an individual	2008	300,000
335b(a)	1,100,000	Per violation for ''any other person''	2008	1,200,000
360pp(b)(1)	1,100	Per violation per person	2008	1,100 (not adjusted)
360pp(b)(1)	330,000	For any related series of violations	2008	355,000
42 U.S.C.				
263b(h)(3)	11,000	Per violation	2008	11,000 (not adjusted)
300aa–28(b)(1)	110,000	Per occurrence	2008	120,000

Dated: October 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–26866 Filed 11–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2004–P–0205 (formerly Docket No. 2004P–0464)]

Food Labeling: Health Claims; Calcium and Osteoporosis, and Calcium, Vitamin D, and Osteoporosis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of Monday, September 29, 2008 (73 FR 56477). The final rule was published with an inadvertent error in the ''Analysis of Economic Impacts'' section. This document corrects that error.

DATES: This correction is effective: November 12, 2008.

FOR FURTHER INFORMATION CONTACT: Jillonne Kevala, Office of Nutrition, Labeling, and Dietary Supplements (HFS–830), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1450.

SUPPLEMENTARY INFORMATION: In FR Doc. E8–22730, appearing on page 56477 in the **Federal Register** of September 29, 2008, the following correction is made:

1. On page 56481, in the second column, starting in the forth line, the sentence ''Therefore, because of the limited use of the current calcium and osteoporosis health claim, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.'' is corrected to read ''Therefore, because of the limited use of the current calcium and osteoporosis health claim, the agency believes that the final rule will not have a significant economic impact on a substantial number of small entities.''

Dated: November 5, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–26868 Filed 11–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 578

Decorations, Medals, Ribbons, and Similar Devices

AGENCY: Department of the Army, DOD.

ACTION: Final rule; removal.

SUMMARY: This action removes 32 CFR Part 578, Decorations, Medals, Ribbons, and Similar Devices. The Department of the Army has determined that the rules prescribing policy and criteria for military awards and the administrative instructions for processing military awards are not required to be published in the Code of Federal Regulations (CFR) because they are not generally applicable and have no legal effect per 44 U.S.C. 1505.

DATES: Effective date November 12, 2008.

ADDRESSES: U.S. Army Human Resources Command, *ATTN:* AHRC–PDP–A, 200 Stovall Street, Alexandria, VA 22332–0471.

FOR FURTHER INFORMATION CONTACT: Mr. Les Plooster, Policy Section, Military Awards Branch, 703–325–4761.

SUPPLEMENTARY INFORMATION: The Deputy Chief of Staff, G–1, is the proponent for the regulation represented in 32 CFR Part 578. The objective of the Department of the Army Military Awards Program is to provide tangible recognition for acts of valor, exceptional service or achievement, special skills or qualifications, and acts of heroism not involving actual combat. Implementation of the program is a command responsibility, with the goal of fostering mission accomplishment by recognizing excellence of both military and civilian members of the force and motivating them to high levels of performance and service. As such, the program does not have the general applicability and legal effect required to publish rules pertaining to this program in the Code of Federal Regulations.

List of Subjects in 32 CFR Part 578

Decorations, Medals, Awards, Military Personnel.

PART 578—[REMOVED]

■ Accordingly, for reasons stated in the preamble, under the authority of Sec. 3012, Public Law 84–1028, 70A Stat. 157, and 10 U.S.C. 3013, 32 CFR Part 578, Decorations, Medals, Ribbons, and Similar Devices, is removed in its entirety.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. E8–26699 Filed 11–10–08; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

RIN 0651–AC28

[Docket No.: PTO–P–2008–0023]

Fiscal Year 2009 Changes to Patent Cooperation Treaty Transmittal and Search Fees

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The United States Patent and Trademark Office (Office) is amending the rules of practice to adjust the transmittal and search fees for international applications filed under the Patent Cooperation Treaty (PCT). The Office is adjusting the PCT transmittal and search fees to recover the estimated average cost to the Office of processing PCT international applications and preparing international search reports and written opinions for PCT international applications.

DATES: *Effective Date:* The changes to 37 CFR 1.445 are effective on January 12, 2009 and are applicable to any international application having a receipt date that is on or after January 12, 2009.

FOR FURTHER INFORMATION CONTACT: Boris Milef, Legal Examiner, Office of PCT Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, by telephone at (571) 272–3288; or by mail addressed to: Box Comments Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450.

SUPPLEMENTARY INFORMATION: The PCT enables United States applicants to file one application (a PCT international application) in a standardized format in English in a Receiving Office (either the United States Patent and Trademark Office or the International Bureau of the World Intellectual Property