procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' 5 U.S.C. 553(b)(A) and (B). The APA also requires that rules generally be published not less than 30 days before their effective date. *See* 5 U.S.C. 553(d). As with the notice and comment requirement, however, the APA provides an exception when ''otherwise provided by the agency for good cause found and published with the rule.'' 5 U.S.C. 553(d)(3).

TILA does not require Board to provide notice or a hearing with respect to this rulemaking. *See* TILA Section 105(a), 15 U.S.C. 1604(a). The revisions made to the commentary by this final rule are interpretative and merely explain that the April 1, 2011, mandatory compliance date that was specified in September 2010 was subsequently changed as a result of the Court's issuance of a temporary administrative stay. The Board finds that there is good cause to conclude that providing notice and an opportunity to comment before issuing this final rule is unnecessary and that there is good cause for the final rule to be effective immediately. The change that is noted in this final rule has already occurred as a result of the Court's prior order. The final rule merely makes conforming changes so that the commentary accurately reflects the effect that the Court's order had on mandatory compliance date.

List of Subjects in 12 CFR Part 226

Advertising, Consumer protection, Federal Reserve System, Mortgages, Reporting and recordkeeping requirements, Truth in lending.

Text of Final Revisions

For the reasons set forth in the preamble, the Board amends Regulation Z, 12 CFR part 226, as set forth below:

PART 226—TRUTH IN LENDING (REGULATION Z)

■ 1. The authority citation for part 226 continues to read as follows:

Authority: 12 U.S.C. 3806; 15 U.S.C. 1604, 1637(c)(5), and 1639(l); Pub. L. 111–24 § 2, 123 Stat. 1734; Pub. L. 111–203, 124 Stat. 1376.

■ 2. In Supplement I to part 226, in Subpart E, under *Section 226.36—Prohibited Acts or Practices in Connection With Credit Secured by a Dwelling,* revise paragraph 2 to read as follows:

Supplement I To Part 226—Official Staff Interpretations

* * * * *

Subpart E—Special Rules for Certain Home Mortgage Transactions

* * * * *

Section 226.36—Prohibited Acts or Practices in Connection with Credit Secured by a Dwelling

* * * * *

2. *Mandatory compliance date for §§ 226.36(d) and (e).* The final rules on loan originator compensation in § 226.36 apply to transactions for which the creditor receives an application on or after the effective date. For example, assume a mortgage broker takes an application on March 10, 2011, which the creditor receives on March 25, 2011. This transaction is not covered. If, however, the creditor does not receive the application until April 8, 2011, the transaction is covered.

* * * * *

By order of the Board of Governors of the Federal Reserve System, acting through the Director of the Division of Consumer and Community Affairs under delegated authority, July 14, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–18215 Filed 7–19–11; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 187

[Docket No.: FAA–2010–0326; Amendment No. 187–35]

RIN 2120–AJ68

Update of August 2001 Overflight Fees

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This final rule updates existing Overflight Fees using more current FAA cost accounting data and air traffic activity data. Overflight Fees are charges for aircraft flights that transit U.S.-controlled airspace, but neither land in nor depart from the United States. These fees have not been updated in nearly a decade and are based upon 1999 cost accounting and activity data. This action is necessary because operational costs have increased steadily since the fees were last updated. This adjustment of Overflight Fees will result in an increased level of cost recovery for the services being provided.

DATES: Effective October 1, 2011.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this final rule, contact David Rickard, Office of Financial Controls, Financial Analysis Division (AFC 300), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 493–5480; e-mail to *david.rickard@FAA.gov.*

For legal questions concerning this final rule contact Michael Chase, AGC–240, Office of Chief Counsel, Regulations Division, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–3110; e-mail to *michael.chase@faa.gov.*

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to establish these fees is found in Title 49 of the United States Code. This rulemaking has been conducted under the authority described in Chapter 453, Section 45301 *et seq.* Under that Chapter, the FAA is charged with prescribing regulations for the collection of fees for air traffic control and related services provided to aircraft, other than military and civilian aircraft of the United States Government or a foreign government, that transit U.S.-controlled airspace, but neither take off from nor land in the United States (''Overflights''). This final rule is within the scope of that authority.

Background

The FAA's Overflight Fees were initially authorized in the Federal Aviation Reauthorization Act of 1996 (Pub. L. 104–264, enacted October 9, 1996). Following enactment of the initial fee authority, and as mandated by that authority, the FAA issued an Interim Final Rule (IFR), ''Fees for Air Traffic Services for Certain Flights through U.S.-Controlled Airspace'' (62 FR 13496), on March 20, 1997. Under the terms of the IFR, the FAA sought public comment on the IFR while concurrently beginning to assess Overflight Fees 60 days after its publication, on May 19, 1997.

On July 17, 1997, petitions for judicial review of the IFR were filed in the U.S. Court of Appeals for the District of Columbia (the Court) by the Air Transport Association of Canada (ATAC) and seven foreign air carriers. Those petitions were consolidated into a single case (*Asiana Airlines* v. *FAA,* 134 F.3d 393 (DC Cir. 1998)). The litigation proceeded throughout the remainder of 1997 while the FAA continued to collect fees pursuant to the statute.

On January 30, 1998, the Court issued a decision, upholding the FAA on three process and procedure issues, but vacating the Rule because the Court

found that the methodology the FAA used to allocate costs did not conform to the statute. The FAA immediately suspended billing operations, and eventually refunded nearly $40 million in fees that had been collected.

Although the 1997 IFR (62 FR 13496) had been set aside by the Court, the statutory requirement that the FAA establish Overflight Fees through an IFR remained in effect. One of the principal criticisms the FAA had received in the public comments on its 1997 IFR concerned the quality of the cost information upon which the Overflight Fees were based. The FAA had already begun developing a new Cost Accounting System (CAS) in 1996. Early data from the new CAS was becoming available in 1998. Thus, when the FAA decided, following the initial litigation, to issue a new IFR, a key element of that decision was that the fees would be derived from cost data from the new CAS.

A new IFR was published in the **Federal Register** on June 6, 2000 (65 FR 36002), with fees scheduled to go into effect on August 1, 2000. This new IFR was challenged in court by the ATAC and a slightly different group of seven foreign air carriers. The FAA began assessing and collecting the new Overflight Fees as scheduled on August 1, 2000, while public comments were still being received by the FAA on its second IFR. The litigation proceeded concurrently, with oral arguments held on May 14, 2001.

On July 13, 2001, the Court again vacated the FAA's IFR, this time because the Court believed the FAA had failed to explain a key assumption in its costing methodology. (*Air Transport Association of Canada* vs. *FAA;* 00–1344, July 13, 2001). Under the Court's order, there were 45 days before the IFR was to be vacated. As noted above, the FAA had solicited public comment on the IFR at the time it was published. The FAA had received many comments on the several issues raised in the litigation. At the time the Court's decision was issued, the FAA was nearing completion of a Final Rule that would address these issues in the disposition of public comments section of the Rule.

The FAA therefore proceeded on two fronts. It successfully petitioned the Court not to vacate the IFR while it proceeded concurrently with issuance of the Final Rule (''Fees for FAA Services for Certain Flights,'' 66 FR 43680) on August 20, 2001, with revised fees effective immediately. In addition to addressing the public comments received on the IFR, the Final Rule reduced fees by about 15 percent due to adjustments in the original cost data. A new challenge to the revised fees was brought after the issuance of the Final Rule by ATAC and the same group of air carriers. The two cases, one challenging the IFR (65 FR 36002) issued in 2000 and the other challenging the Final Rule (66 FR 43680) issued in 2001, were combined by the Court into a single case.

While the litigation was still pending, on November 19, 2001, Congress enacted the Aviation and Transportation Security Act (ATSA), which included a provision that amended the Overflight Fee authorization: (1) To require that the fees be ''reasonably'' (rather than ''directly'') related to costs; (2) to clarify that the Administrator has sole authority to determine the costs upon which the fees are based; and (3) to state explicitly that such cost determinations by the Administrator are not subject to judicial review. Meanwhile, the litigation proceeded into 2003, with the FAA continuing to collect the fees as required by statute.

On April 8, 2003, the Court issued a decision setting aside the Final Rule and remanding it back to the FAA, finding that the agency had not adequately explained its handling of controller labor costs in deriving the fees. (*Air Transport Association of Canada* v. *FAA,* 323 F.3d 1093 (DC Cir. 2003)). The Court also found that the Overflight Fees amendments in the ATSA statute were inapplicable because of a generic ''savings'' provision in the ATSA legislation that stated that nothing enacted in ATSA was applicable to any litigation ongoing prior to the date of enactment of ATSA. Fee collections were immediately suspended.

On December 12, 2003, Congress enacted VISION 100—CENTURY OF AVIATION REAUTHORIZATION ACT, (Vision 100). Section 229 of that Act explicitly ''adopted, legalized, and confirmed'' both the IFR published in 2000 and the Final Rule published in 2001. In addition, the FAA was directed to hold a consultation meeting with users (those who pay the Overflight Fees to the FAA) and to submit a report to Congress addressing the issues that had been in dispute in the litigation before resuming the billing and collection of the Overflight Fees.

Because there were ambiguous and potentially conflicting provisions in Vision 100 concerning Overflight Fees, the Administrator issued an Order on July 21, 2004, that set forth her interpretation of the language of the statute and, based on that interpretation, made determinations as to the ultimate disposition of Overflight Fees collected by the FAA under both the 2000 IFR and the 2001 Final Rule. The FAA retained a portion of the funds collected under the Final Rule, while either refunding or providing credits to the airlines for all of the fees collected under the IFR and a portion of the fees collected under the Final Rule. A copy of that Order, ''Order Directing the Disposition of Certain Fees Collected by the Federal Aviation Administration Pursuant to 49 USC Section 45301,'' was published in the **Federal Register** on August 4, 2004 (69 FR 47201).

The FAA met with users in September 2004 and submitted a report to Congress at the same time, as mandated by the Vision 100 statute. This cleared the way for the FAA to resume the billing and collection of Overflight Fees. In most cases, amounts previously collected by the FAA under the IFR and under the Final Rule up until the date of the ATSA enactment were provided as credits to frequent payers. These amounts were, in most cases, roughly offset by amounts owed by the carriers and other users for the 1-year period from March 2003 through February 2004. The carriers had not been billed for this period while the litigation was ongoing, but were ultimately determined by the Administrator to be liable for those fees.

Since that time, the FAA has followed the normal process of issuing monthly bills for the services provided to Overflights. The fees currently being charged were derived from cost and activity data for FY 1999. This Final Rule updates the existing fees by using cost and activity data for FY 2008 to derive the fees. The cost methodology applied in this Final Rule is applied in the same manner as in 2001, except that overhead has been included in the cost base for the fees this time as a direct result of the ATSA amendment that changed the previous statutory requirement that fees be ''directly'' related to costs to a less stringent requirement that the fees be ''reasonably'' related to costs.

The FAA's CAS has been evolving and improving over time. The CAS has always relied on the best available data, and as new systems and techniques have evolved, the quality and accuracy of the data has improved. There are areas, such as the reporting of labor costs, where costs were allocated or assigned in the past based on estimates, but today are determined by actual data. This is not a difference in how the data are gathered, but rather an improvement in the quality and accuracy of the basic data. A detailed explanation of how the CAS data were assembled can be found in the ''Costing Methodology Report, FY

2008,'' which has been placed in the docket for this rulemaking.

The evolution and improvement of the FAA's financial management practices over time, including its cost accounting, is worth noting. Following several years in the early days of the CAS, in which the FAA's auditors reported material weaknesses in areas including cost accounting information and accounting for property, plant, and equipment, the FAA received unqualified audit opinions on its financial statements in 9 of the last 10 years (FYs 2001–2010). The auditor's opinion for FY 2006 was initially qualified due to untimely processing of transactions and accounting for construction in progress, but was revised the following year to an unqualified audit opinion after the FAA corrected and restated its FY 2006 financial statements. Thus, following the restatement and revised auditor's opinion, the FAA's financial statements have been unqualified for 10 years. It is also significant that, in 5 of those 10 years, including the last 3, those unqualified opinions were ''with no material weaknesses.''

This continuing improvement in the quality and transparency of the FAA's financial statements is a significant contributing factor to the fact that the Association of Government Accountants has awarded the Certificate of Excellence in Accountability Reporting (CEAR) to the FAA for its Performance and Accountability Reports in 7 of the last 8 years (FYs 2003–2010). The CEAR is considered the highest form of recognition for Federal Government financial management reporting.

Overflight Fees Aviation Rulemaking Committees (ARC)

In 2004, the FAA established an Overflight Fees ARC. That Committee held two meetings in early 2005, but never issued a report or made a recommendation to the FAA before its Charter expired. Subsequently, on December 17, 2008, the FAA issued a new Charter for an Overflight Fees ARC to advise and make recommendations to the FAA on the updating of its Overflight Fees. At the same time, the FAA initiated a rulemaking project to update the Overflight Fees, with the expectation that the activities and the end product(s) of the ARC deliberations would likely become an integral part of this rulemaking. The Overflight Fees ARC met several times in 2009 and issued its report and recommendations to the FAA on August 26, 2009. A copy of this report has been placed in the docket. The report contains three principal recommendations: (1) That the FAA pursue the updating of its Overflight Fees through the normal notice and comment type of rulemaking, rather than through the interim final rule process previously mandated by Congress; (2) that, in updating the fees, the FAA abide by the policies of the International Civil Aviation Organization (ICAO), whereby the principle of gradualism is applied so that any substantial fee increase (as in this case where a 9-year update is involved) is spread over several years; and (3) that, in this instance, the specific increases be accomplished over 4 increments, on October 1st of each year from 2011 through 2014, with annual increases of 14% for Enroute and 8% for Oceanic.

After a careful and thorough review by the FAA of the ARC report and recommendations, the FAA concluded that the ARC recommendations provide a reasonable and workable framework for moving forward on a consensus basis to update the Overflight Fees. Thus, the FAA proceeded to draft a notice of proposed rulemaking (NPRM) to update the fees by implementing the three recommendations of the ARC.

Summary of the Notice of Proposed Rulemaking (NPRM)

The NPRM laid out an explicit plan to update the Overflight Fees by implementing the three ARC recommendations. This would be accomplished by increasing the fees in four annual increments to the amounts that would have produced full cost recovery in FY 2008. The fee levels that would eventually be achieved reflect increases above current levels of 69% in the Enroute environment and 36% in Oceanic. This would be accomplished by increasing the fees on October 1 in each of the years 2011 through 2014 at annual compounded rates of 14% for Enroute and 8% for Oceanic. The actual dollar amounts of each fee as of each of the four October 1st fee revision dates would be as follows:

Fee revision date	Enroute (per 100 nautical miles)	Oceanic (per 100 nautical miles)
October 1, 2011	$38.44	$17.22
October 1, 2012	43.82	18.60
October 1, 2013	49.95	20.09
October 1, 2014	56.86	21.63

The NPRM was published in the **Federal Register** on September 28, 2010, with public comments due in 90 days, on December 27, 2010 (75 FR 59661). A more detailed discussion of the specifics of the fee update proposal can be found in that document.

Disposition of Comments

The FAA received only one letter of comment on the NPRM. That letter was from Lufthansa German Airlines, and was signed by the individual who had served as the Lufthansa representative on the aforementioned ARC on Overflight Fees. While the letter stated clearly that Lufthansa supports the ARC process and the recommendations of the ARC, it nevertheless went on to identify four topics that it believed should be further examined by the FAA before proceeding with any increase of the existing Overflight Fees. Those four topics are listed below, followed in each case by the FAA's response to the comment.

1. Enroute Costs for Air Traffic Control (ATC) Services in Lower Airspace

Noting that there are low activity airports and airfields that are not served by a terminal radar approach control (TRACON) or an air traffic control tower and that, in these instances, ATC services are provided by Enroute controllers, Lufthansa asserts that the costs of these Enroute controllers should be removed from the Enroute (and thus the Overflight Fee) cost base.

The FAA does not agree with Lufthansa's assertion. The FAA notes that while there are low activity airports and airfields where traffic is controlled by Enroute controllers, the level of such activity is low enough that it does not require increased staffing and thus the costs of such services are *de minimis.* This issue was addressed by the FAA's cost accounting team at the time the Cost Accounting System was being developed. This information was

derived from conversations between the cost accounting team and the Air Route Traffic Control Center (ARTCC) managers. The team determined that there was not a significant amount of Enroute controller time spent on aircraft in lower airspace.

The FAA's Air Traffic Organization (ATO) costs do not vary with the altitude of an aircraft. The infrastructure costs are mostly fixed (*e.g.,* the building is there, the radars are operational, the communication lines are open, the automation system processes the radar targets, and the environmental systems are operational). The costs of controllers in the short term are also fixed. They are paid based on the volume and complexity of the work at the facility to which they are assigned, whether they work a single aircraft or numerous aircraft in a given period of time, and whether those aircraft are in straight and level flight or are in transition. The fact that the job may be more complex at the moment because of crossing traffic or transitioning traffic does not drive their costs. The workload is very dynamic in the radar environment, but a controller costs the same to the ATO whether he or she is working a complex sector at a busy time of day or a less busy sector after the push of traffic is over.

2. Costs of Flow Control

Lufthansa states that there are controllers in most, and possibly all, FAA Centers who are working ''flow control'' and that the work of these controllers does not benefit the overflight traffic and should therefore be removed from the Enroute (and thus the Overflight Fee) cost base.

The FAA disagrees. As discussed at some length in the Introduction, Overview, and Background sections of the current Final Rule on Overflight Fees (66 FR 43680–43681), the FAA air traffic control system is a large, complex, integrated system with many components, all of which must work together for the benefit of all users, whether they be overflights or non-overflights. Flow control is a small but important and integral part of that system, and benefits all users, including overflights. For example, when weather conditions necessitate changes in the routing and management of air traffic, it is all traffic, overflights and non-overflights, that are affected. There is no rational reason for excluding flow control costs from the Enroute cost base. Moreover, the costs of air traffic flow management are an explicitly allowable item of cost for cost recovery purposes under the International Civil Aviation Organization's (ICAO) Policies on Charges for Airports and Air Navigation Services (*See ICAO Document 9082*).

3. Overhead Costs

Lufthansa notes that the FAA is a large, multi-faceted organization, and suggests, for that reason, it is difficult to properly allocate the correct amount of overhead to the air navigation activity, and suggests that FAA the ''only allocate overhead using a marginal cost approach.''

The FAA does not agree with Lufthansa's suggestion. The FAA believes the allocation of FAA overhead costs is in accordance with generally accepted accounting practices. The Lufthansa comments on this topic suggest a possible misunderstanding of how FAA overhead is allocated and assigned, although it was discussed in meetings of the ARC and was addressed in a set of questions given to the FAA by the ARC and answered by the FAA. For example, Lufthansa appears to believe that the presence of other aviation related activities, such as Airport Grants and Standards and Aviation Safety, results in the assignment of some of their costs to the air traffic control activity. That is not the case. Both Airports and Aviation Safety are separate FAA Lines of Business (LOB) that are themselves the recipient of their own shares of overhead, and their costs are kept separate and are not allocated or assigned to the air traffic cost pool. The specific details of how FAA overhead is allocated and assigned to the Air Traffic LOB are set forth in the next several paragraphs, and all of this is explained in greater detail in the Costing Methodology Report that has been placed in the docket for this rulemaking.

The FAA overhead allocation can be described in two steps: (1) FAA Headquarters and Regional Overhead; and (2) ATO Overhead.

(1) *FAA Headquarters and Regional Overhead.* A series of *pro rata* allocations are performed in the Cost Accounting System (CAS) to assign the FAA headquarters indirect costs to projects, service delivery points (SDPs), and services within each LOB and other Regional and Center Operations. Then, a series of *pro rata* allocations are made to assign the Aeronautical Center (AMC) indirect costs to projects, SDPs, and services within each LOB located at the Aeronautical Center. Note that not all LOBs track costs at a service and/or SDP level. In these cases, costs are assigned at the project level.

The FAA Headquarters Overhead (excluding human resources) is assigned to projects, SDPs, and services within each LOB based on a percentage of total direct cost. Human resources services indirect costs are assigned to projects, SDPs, and services within each LOB based on the percentage of direct labor cost. The portion of the AMC cost assigned to each LOB is based on the percentage of total cost assigned to each LOB.

FAA Regional Overhead costs represent the indirect cost of FAA general and administrative services provided to the lines of business by personnel residing at FAA regional headquarters offices. A series of *pro rata* allocations are performed in the CAS to assign the FAA regional overhead costs to projects, SDPs, and services based on a percentage of total direct cost within the regions.

(2) *ATO Overhead.* The ATO overhead allocation can be described in three kinds of allocation steps: (i) Service Area Indirect, (ii) Service Unit Indirect and (iii) ATO Indirect.

(i) Service Area Indirect. A *pro rata* allocation is performed in the CAS to assign each Service Area's indirect costs to the direct projects, SDPs, and services that they support. The portion of the cost that is assigned to each project, SDP, and service is determined based on the percentage of total direct cost that is assigned to each project, SDP, and service for that Service Area.

(ii) Service Unit Indirect. A *pro rata* allocation is performed in the CAS to assign each Service Unit's Headquarters' indirect costs to the direct projects, SDPs, and services that they support. The portion of the cost that is assigned to each project, SDP, and service is determined based on the percentage of total direct cost that is assigned to each project, SDP, and service for that Service Unit.

(iii) ATO Indirect. A *pro rata* allocation is performed in the CAS to assign each of ATO's staff offices' indirect costs to the projects, SDPs, and services of all Service Units. The portion of the cost that is assigned to each project, SDP, and service is determined based on the percentage of total direct cost that is assigned to each project, SDP, and service of each Service Unit.

As a final point on the subject of inclusion of overhead in the cost base for Overflight Fees, it should be noted that all overhead costs were excluded from the cost base for the previous Final Rule because the applicable statutory standard at that time required that the fees be ''directly related'' to the costs of the ATC services provided or made available. Congress has since changed that statutory standard to ''reasonably related.'' In light of this change, the FAA believes it is reasonable to include

overhead in the cost base. That is in accordance with generally accepted accounting practices as well as with guidance on fee setting issued by ICAO (Policies on Charges for Airports and Air Navigation Services, Document 9082).

4. Overflight Fees and the ''Fairness'' of the International Aviation Tax

Lufthansa asserts that, based on its own analysis of its international trans-Atlantic flights to and from the United States (non-overflights), the passengers on those flights are ''overpaying'' taxes into the Airport & Airway Trust Fund by at least a factor of four. For that reason, they argue that charging an ''increased overflight fee renders the system even more unfair.''

The FAA believes this comment is beyond the scope of this rulemaking. The ''fairness'' of the international aviation taxes has nothing to do with the validity of, or justification for, an increase in Overflight Fees. The two are unrelated. Aviation tax levels are set by the U.S. Congress and are beyond the control of the FAA. Similarly, Congress has directed the FAA to establish cost-based Overflight Fees. Therefore, to retain the cost-based relationship, the FAA must periodically review and revise its Overflight Fees. Fairness of the aviation taxes notwithstanding, the FAA is obliged to update its Overflight Fees.

In conclusion, the FAA does not believe any of the four points raised by Lufthansa and discussed in this section require any change in the process and specificity of the Overflight Fee update proposed in the NPRM. Accordingly, the FAA is adopting the amendment to Appendix B to Part 187—Fees for FAA Services for Certain Flights as proposed in the NPRM without change.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there is no new requirement for information collection associated with this final rule. The information used to track overflights (including the information collection necessary to implement this final rule) can be accessed from the flight plans filed with the FAA. The collection of information from the Domestic and International Flight Plans is approved under OMB Collection Control #2120–0026.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has reviewed the corresponding ICAO Standards and Recommended Practices and has identified no differences with these regulations.

Regulatory Evaluation, Regulatory Flexibility Determination, International Trade Impact Assessment, and Unfunded Mandates Assessment

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this proposed rule.

Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits a statement to that effect and the basis for it to be included in the preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for this final rule. The reasoning for this determination follows:

Benefit

The benefit of this final rule will be that the overflight fees will be more closely related to the actual costs of providing FAA's services for these flights.

Costs

Taxes and government fees are transfer payments, and, by OMB directive, transfers are not considered a societal cost. Therefore, this rule imposes no costs. We do provide an estimate of the transfers. There will be a 4-year phase-in of fees with yearly increases (14% Enroute and 8% Oceanic). Increases would begin in 2011 and end in 2014. We have determined that approximately 80% of Overflight Fees for domestic operators will be Enroute and 20% will be Oceanic (see Table 1).

Most of the transfers from this final rule will be borne by foreign operators. The estimated transfers from this final rule from foreign operators to the FAA are about $73 million ($52 million, present value). See Table 2.

The FAA estimates that the total transfers resulting from this final rule from U.S. entities to the FAA over 5 years will be about $1.1 million ($0.8 million, present value). Again, government fees and taxes are considered transfers and not societal costs, so this final rule does not increase society's costs.

Table 1. Domestic Operators' Overflight Fees

Oceanic	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2011-2015
Current Fees (20%)	$152,612	$152,612	$152,612	$152,612	$152,612	$763,059
Proposal	$152,612	$164,821	$178,006	$192,247	$207,627	$895,312
Incremental Transfer	$0	$12,209	$25,395	$39,635	$55,015	$132,254
EnRoute	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2011-2015
Current Fees (80%)	$610,447	$610,447	$610,447	$610,447	$610,447	$3,052,236
Proposal	$610,447	$695,910	$793,337	$904,404	$1,031,021	$4,035,119
Incremental Transfer	$0	$85,463	$182,890	$293,957	$420,574	$982,883
Total Incremental Transfers	$0	$97,672	$208,285	$333,592	$475,589	$1,115,137
PV Transfers	$0	$79,729	$158,899	$237,847	$316,905	$793,380

Table 2. Foreign Operators' Overflight Fees

Oceanic	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2011-2015
Current Fees	$21,640,240	$21,640,240	$21,640,240	$21,640,240	$21,640,240	$108,201,200
Proposal	$21,640,240	$23,371,459	$25,241,176	$27,260,470	$29,441,308	$126,954,653
Incremental Transfer	$0	$1,731,219	$3,600,936	$5,620,230	$7,801,068	$18,753,453
EnRoute	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2011-2015
Current Fees	$33,784,067	$33,784,067	$33,784,067	$33,784,067	$33,784,067	$168,920,335
Proposal	$33,784,067	$38,513,836	$43,905,773	$50,052,582	$57,059,943	$223,316,202
Incremental Transfer	$0	$4,729,769	$10,121,706	$16,268,515	$23,275,876	$54,395,867
Total Incremental Transfers	$0	$6,460,989	$13,722,642	$21,888,745	$31,076,944	$73,149,320
PV Transfers	$0	$5,274,091	$10,468,938	$15,606,373	$20,707,880	$52,057,282

The FAA has, therefore, determined that this final rule is not an economically ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866 and is not ''significant'' as defined in DOT's Regulatory Policies and Procedures.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation.'' To achieve that principle, the RFA requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the Act.

The FAA ranked in descending order all domestic entities based on their Overflight Fees. Then we identified 5 small entities having publicly-available financial information (using a size standard of 1,500 or fewer employees) in the top 20 percent of the ranking. We retrieved their annual revenue from World Aviation Directory and compared it to their annualized compliance costs. Of these 5 entities, all of them have annualized compliance costs as a percentage of annual revenues lower than 0.1 percent. We believe this economic impact is not significant. Furthermore, we received no comments from small entities in response to the NPRM. Consequently, as the FAA Administrator, I certify that the final rule will not have a significant economic impact on a substantial number of small entities.

International Trade Impact Analysis

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this final rule and determined that it will primarily affect foreign users, generally commercial operators. Foreign operators are charged a fee only if they overfly (do not land in) the United States. The FAA believes it is highly unlikely that foreign commercial users will alter their behavior to avoid paying the fees. We believe that the final rule could enhance the competitiveness of domestic commercial operators relative to international carriers.

Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State,

local, and Tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $140.8 million in lieu of $100 million. This final rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have federalism implications.

Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 312d and involves no extraordinary circumstances.

Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). We have determined that it is not a ''significant energy action'' under the executive order and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Availability of Rulemaking Documents

You can get an electronic copy of rulemaking documents using the Internet by—

1. Searching the Federal eRulemaking Portal (*http://www.regulations.gov*);

2. Visiting the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies/* or

3. Accessing the Government Printing Office's Web page at *http://www.gpoaccess.gov/fr/index.html.*

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–9680. Make sure to identify the notice, amendment, or docket number of this rulemaking.

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://DocketsInfo.dot.gov.*

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. If you are a small entity and you have a question regarding this document, you may contact your local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. You can find out more about SBREFA on the Internet at *http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 187

Administrative practice and procedure, and Air transportation.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends Chapter I of Title 14, Code of Federal Regulations, as follows:

PART 187—FEES

■ 1. The authority citation for part 187 continues to read as follows:

Authority: 31 U.S.C. 9701, 49 U.S.C. 106(g), 49 U.S.C. 106(l)(6), 40104–401–5, 40109, 40113–40114, 44702.

■ 2. In part 187, Appendix B is amended by revising paragraph (e)(2) to read as follows:

Appendix B to Part 187—Fees for FAA Services for Certain Flights

* * * * *

(e) * * *

(2) A User (operator of an Overflight) is assessed a fee for each 100 nautical miles (or portion thereof) flown in each segment and type of U.S.-controlled airspace. Separate calculations are made for transiting Enroute and Oceanic airspace. The total fee charged for an Overflight between any entry and exit point is equal to the sum of these two charges. This relationship is summarized as:

$R_{ij} = X*DE_{ij} + Y*DO_{ij}$,

Where:

R_{ij} = the fee charged to aircraft flying between entry point i and exit point j,

DE_{ij} = total great circle distance traveled in each segment of U.S.-controlled Enroute airspace expressed in hundreds of nautical miles for aircraft flying between entry point i and exit point j for each segment of Enroute airspace.

DO_{ij} = total great circle distance traveled in each segment of U.S.-controlled Oceanic airspace expressed in hundreds of nautical miles for aircraft flying between entry point i and exit point j for each segment of Oceanic airspace.

X and Y = the values respectively set forth in the following schedule:

Time period	X (enroute)	Y (oceanic)
Through September 30, 2011	$33.72	$15.94
October 1, 2011 through September 30, 2012	38.44	17.22
October 1, 2012 through September 30, 2013	43.82	18.60
October 1, 2013 through September 30, 2014	49.95	20.09
October 1, 2014 and beyond	56.86	21.63

* * * * *

Issued in Washington, DC, on July 13, 2011.

J. Randolph Babbitt,

Administrator.

[FR Doc. 2011–18285 Filed 7–19–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2011–N–0499]

Medical Devices; General and Plastic Surgery Devices; Classification of the Focused Ultrasound Stimulator System for Aesthetic Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the focused ultrasound stimulator system for aesthetic use into class II (special controls). The special control(s) that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use.'' The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This rule is effective August 19, 2011. The classification was effective on September 11, 2009.

FOR FURTHER INFORMATION CONTACT: Richard Felten, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1436, Silver Spring, MD 20993–0002, 301–796–6392.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the FD&C Act. FDA will, within 60 days of receiving this request, classify the device by written order. This classification will be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on March 14, 2008 classifying the Ulthera™ Focused Ultrasound Stimulator System for Aesthetic Use into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On April 11, 2008, Ulthera, Inc. submitted a petition requesting classification of the Ulthera™ Focused Ultrasound Stimulator System for Aesthetic Use under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name Focused Ultrasound Stimulator System for Aesthetic Use and it is identified as a device using focused ultrasound to produce localized, mechanical motion within tissues and cells for the purpose of producing either localized heating for tissue coagulation or for mechanical cellular membrane disruption intended for noninvasive aesthetic use.

FDA has identified the following risks to health associated specifically with this type of device and the recommended measures to mitigate these risks.

- Thermal injury from focused ultrasound exposure (thermal damage), such as erythema, edema, pigmentary changes, and pain. These are commonly seen risks associated with any energy delivery system that creates tissue heating. This risk is addressed by recommended treatment parameters that have been shown to be safe with little or no adverse effects. In addition, the recommended labeling includes warnings related to patient reaction in terms of pain and information to user in terms of observable skin reactions that are known to be precursors to the potential thermal adverse effects.
- Mechanical injury from focused ultrasound exposure (mechanical damage) induced by either cavitation or noncavitation means. Notable effects are pain and petechial hemorrhage (red spots). Further, skin contour changes due to scar formation are possible. This risk is addressed by recommended treatment parameters that have been shown to be safe with little or no adverse effects.
- Ocular injury represents a potentially unique serious risk from inadvertent ultrasound exposure. The mitigation of this risk is addressed by labeling recommendations to warn the user not to expose the eye to ultrasound radiation, as well as specific directions intended to ensure complete handpiece skin contact, which further reduces the risk of scattered ultrasound energy reaching the eye.
- Electrical shock is addressed by recommended testing of the device according to recognized U.S. and International Standards specifically designed to determine and measure potential electrical safety. Again, the recommended device labeling also includes specific warnings for the user in terms of device placement, appropriate electrical wiring needs, reminders to periodically check device wiring and accessories for damage, and avoidance of use of the device in