

service after the effective date of this AD, install a protector on the fuel shut-off control according to the instructions of Robin Aviation Imperative Service Bulletin No. 180, dated March 20, 2001.

#### FAA AD Differences

**Note:** This AD differs from the MCAI and/or service information as follows: No differences.

#### Other FAA AD Provisions

(f) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Staff, FAA, Small Airplane Directorate, ATTN: Karl Schletzbaum, Aerospace Engineer, 901 Locust, Room 301, Kansas City, MO 64106; telephone: (816) 329-4146; fax: (816) 329-4090, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

#### Related Information

(g) Refer to MCAI Civil Aviation Authority AD DCA/R2000/32, Effective Date: June 29, 2006, and Robin Aviation Imperative Service Bulletin No. 180, dated March 20, 2001, for related information.

Issued in Kansas City, Missouri, on December 28, 2006.

**John Colomy,**

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. E6-22623 Filed 1-4-07; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Parts 47, 61, 63, and 65

[Docket No. FAA-2006-26714; Notice No. 06-21]

**RIN 2120-A143**

#### Drug Enforcement Assistance

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** The FAA is proposing changes to its airmen certification and aircraft registration requirements. Two years after the final rule becomes effective, paper pilot certificates may no longer be used to exercise piloting privileges. Five years after the final rule becomes effective, certain other paper airmen certificates, such as those of flight engineers and mechanics, may no longer be used to exercise the privileges authorized by those certificates. To exercise the privileges after those respective dates, the airmen would have to hold upgraded, counterfeit-resistant plastic certificates. Student pilots would not be affected. In addition, those who transfer ownership of U.S.-registered aircraft would have five days from the transaction to notify the FAA Aircraft Registry. Those who apply for aircraft registration would have to include their printed or typed name with their signature. These changes are responsive to concerns raised in the FAA Drug Enforcement Assistance Act. The purpose of the changes is to upgrade the quality of data and documents to assist Federal, State, and local agencies to enforce the Nation's drug laws.

**DATES:** Send your comments to reach us by March 6, 2007.

**ADDRESSES:** You may send comments, identified by Docket Number FAA-2006-, using any of the following methods:

- *DOT Docket Web site:* Go to <http://dms.dot.gov> and follow the instructions for sending your comments electronically.

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL-401, Washington, DC 20590-001. Note that mail delivery may be delayed due to security concerns.

- *Fax:* 1-202-493-2251.

- *Hand Delivery:* Room PL-401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For more information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

*Privacy:* We will post all comments we receive, without change, to <http://dms.dot.gov>, including any personal information you provide. For more information, see the Privacy Act discussion in the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* To read background documents or comments received, go to

<http://dms.dot.gov> at any time or to Room PL-401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

#### FOR FURTHER INFORMATION CONTACT:

Mark D. Lash, Civil Aviation Registry, Mike Monroney Aeronautical Center, 6500 South MacArthur Boulevard, Oklahoma City, OK 73169, telephone (405) 954-4331.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. Please include the regulatory docket or amendment number on your comments, and if you mail or hand deliver your comments, send two copies. We will file all comments received, as well as a report summarizing each substantive public contact with FAA personnel on this rulemaking, in the public docket. The docket is available for public inspection before and after the comment closing date.

*Privacy Act:* Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment 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 (65 FR 19477-78) or you may visit <http://dms.dot.gov>.

Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

If you mail your comments and want the FAA to acknowledge receipt of the comments, you must include with your comments a preaddressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2006-26714." We will date stamp the postcard and mail it to you.

### Proprietary or Confidential Business Information

Do not file in the docket information that you consider to be proprietary or confidential business information. Send or deliver this information directly to the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this document. You must mark the information that you consider proprietary or confidential. If you send the information on a disk or CD-ROM, mark the outside of the disk or CD-ROM and also identify electronically within the disk or CD-ROM the specific information that is proprietary or confidential.

Under 14 CFR 11.35(b), when we are aware of proprietary information filed with a comment, we do not place it in the docket. We hold it in a separate file to which the public does not have access and place a note in the docket that we have received it. If we receive a request to examine or copy this information, we treat it as any other request under the Freedom of Information Act (5 U.S.C. 552). We process each request to examine or copy information marked as proprietary or confidential under the DOT procedures found in 49 CFR part 7.

### Availability of Rulemaking Documents

You can get an electronic copy of this NPRM using the Internet by:

- (1) Searching the Department of Transportation's electronic Docket Management System (DMS) Web page (<http://dms.dot.gov/search>);
- (2) Visiting the Office of Rulemaking's Web page at <http://www.faa.gov/avr/arm/index.cfm>; 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 docket number, notice number, or amendment number of this rulemaking.

### Background

On March 12, 1990, the FAA published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (55 FR 9270). The NPRM proposed changes to certain requirements concerning registration of aircraft, certification of pilots, and penalties for registration and certification violations. The NPRM also announced non-rulemaking procedural changes. We intended the changes to

correct deficiencies in our systems and procedures identified in the FAA Drug Enforcement Assistance Act of 1988 (Pub. L. 100-690) (hereafter, "the Act"). The Act amended FAA's authorizing legislation (49 U.S.C. 40101 *et seq.*) to—

- Declare that it is FAA policy to assist law enforcement agencies in the enforcement of laws that regulate controlled substances, to the extent consistent with aviation safety;
- Modify the aircraft registration system to more effectively serve the needs of buyers and sellers of aircraft, drug enforcement officials, and other users of the system;
- Modify the pilot certification system to more effectively serve the needs of pilots and drug enforcement officials;
- Modify the system for processing major repair and alterations of fuel tanks and fuel systems on aircraft, to more effectively serve users of the system, including drug enforcement officials;
- Establish and collect the fees necessary to cover the costs of issuing aircraft registration certificates, issuing airman certificates for pilots, and processing forms for major repairs and alterations of fuel tanks and fuel systems of aircraft;
- Pursue civil actions and assess civil penalties for violations of the regulations governing registering aircraft and recording aircraft title documents; and
- Create criminal penalties for forgery of airman certificates, false marking of aircraft, and other aircraft registration violations and to make it unlawful for any person to knowingly and willingly operate an aircraft in violation of any requirement for display of navigation or anti-collision lights.

The comment period closed on May 11, 1990. We received 373 comments, very few of which expressed support for the proposed changes. For the most part, commenters believed that the proposed changes would impose burdens only on law-abiding citizens, while criminals would simply circumvent them. As a result, FAA decided to delay the rulemaking process to assess whether specific technological improvements to the FAA Civil Aviation Registry (the Registry) could meet the intent of the Act. We believe we have now fulfilled most requirements of the Act through changes to systems and procedures used by the Registry. For this reason, we have withdrawn the 1990 NPRM in its entirety. Readers interested in the specific actions we have taken to fulfill the requirements of the Act should refer to the notice withdrawing the 1990 NPRM (70 FR 72403, Dec. 5, 2005).

To complete our obligations under the Act, we are proposing to address two deficiencies noted in the Act and not fully addressed through changes made to the Registry. The first issue concerns the proper identification of pilots. Law enforcement agencies must be able to establish the true identity of those who hold pilot certificates. The second issue concerns the timely reporting of aircraft sales or other transfers of ownership. Law enforcement agencies must be able to determine who is the owner of an aircraft, particularly when ownership of the aircraft has recently been transferred. Later in this preamble, we describe the specific changes we are proposing to address these issues.

### Related Rulemaking Activities

The FAA has two ongoing rulemaking activities that relate to airmen certificates and aircraft registration. This NPRM would bring closure to FAA actions related to the FAA Drug Enforcement Assistance Act. The second NPRM will address requirements of the Intelligence Reform and Terrorism Prevention Act of 2004 (Pub. L. 108-458). While both cover issues concerning airmen certificates and aircraft registration, they are each driven by different requirements and circumstances.

During the process of preparing this NPRM for publication in late 2004, Congress passed the Intelligence Reform and Terrorism Prevention Act of 2004. Section 4022 (Improved Pilot Licenses) of that Act requires pilots' certificates be resistant to tampering, alteration, and counterfeiting. The FAA began issuing plastic certificates in July 2003 that are resistant to tampering, alteration, and counterfeiting. This NPRM would establish dates by which paper certificates may not be used to exercise the privileges authorized by the certificates. This will allow the FAA to also meet the first requirement of the Intelligence Reform Act and increase the security of airman certificates in a timely manner.

The Intelligence Reform Act also requires the inclusion of a photograph on pilots' certificates. The FAA is currently working on an NPRM that would establish the regulations and procedures necessary to implement this requirement. We expect to publish the NPRM in the near future. We have already completed a prototype for inclusion of a photograph on an airmen's certificate.

While this NPRM completes action by the FAA on the FAA Drug Enforcement Assistance Act, the FAA is continuing to evaluate other changes to improve data quality of the Registry, possibly

including periodic registration of aircraft. In a post-9/11 environment, there are important benefits that would result from a more up-to-date and accurate Registry.

#### Pilot Identification and Certification

Under our authorizing legislation, the FAA must issue an "airman certificate" to an individual when we find that the individual is qualified for, and physically able to perform the duties related to, the position authorized by the certificate. See 49 U.S.C. 44703. Sometimes people think of a pilot certificate when the words "airmen certificate" are used, even though there are many other categories of airmen. In this preamble, we use the term "airman certificate" to refer generally to all those who hold airmen certificates, including pilots, flight crewmembers other than pilots (such as flight engineers), and airmen other than flight crewmembers (such as air traffic control tower operators and mechanics). When we use the term "pilot certificate" in this preamble, we are referring only to pilots, not to student pilots, flight instructors, flight engineers, or ground instructors who are also regulated under part 61 of Title 14 of the Code of Federal Regulations (14 CFR part 61). The airman certificate must—

- Contain the name, address, and description of the individual to whom the certificate is issued;
- Contain any necessary terms, conditions, and limitations; and
- Specify the capacity in which the holder of the certificate may serve as an airman with respect to an aircraft.

The current regulations and procedures for getting an airman certificate usually require that an applicant pass both a knowledge test and a flight or practical test. The applicant sends the application and supporting documents to an FAA designee, who in turn sends the application to an FAA Flight Standards District Office for review. Alternatively, the applicant may appear before an FAA inspector in the District Office. The District Office forwards the documents to the Registry where the documents are reviewed for compliance with the regulations. If the Registry accepts the documents, it issues the airman certificate and mails it to the applicant.

The FAA Drug Enforcement Assistance Act amended section 44703 to direct the FAA to modify the system for issuing airman certificates to pilots to make the system more effective in serving the needs of pilots and officials responsible for enforcement of laws relating to the regulation of controlled substances. The Act identified a number

of deficiencies and abuses that the modifications must address, including the use of counterfeit and stolen airman certificates by pilots and the submission of unidentifiable names of individuals on applications for registration of aircraft. The Act also amended section 44703 to require the FAA to prescribe regulations to address the abuses and deficiencies.

In 2002, the FAA revised the pilot certificate requirements of part 61 to require a person to carry photo identification when exercising the privileges of the pilot certificate and to present photo identification when requested by law enforcement officials. See 67 FR 65858, October 28, 2002. These changes address security and law enforcement concerns regarding the identification of pilots. Also, in July 2003, the FAA discontinued issuing paper airman certificates and began issuing airman certificates that incorporate a number of security features. The new certificates are made of high-quality plastic card stock and include micro printing, a hologram, and an ultraviolet-sensitive layer that contains certain words and phrases. These new certificates greatly reduce the ability to create counterfeit airman certificates.

As far as airman certificates issued since July 2003 are concerned, these measures address the problem of counterfeit and stolen airman certificates. However, there is no requirement that a holder of a paper airman certificate get a new plastic certificate. So the outstanding paper certificates are all subject to a higher risk of counterfeiting for the foreseeable future. If there were a requirement for a holder of a paper certificate to periodically get a re-issued certificate, such as is the case with driver's licenses issued by most States, the problem of potential counterfeiting would gradually diminish over time. However, there is currently no reissuance requirement for most airman certificates.

For this reason, the FAA is proposing that the holder of a paper pilot certificate may not exercise the privileges of the paper certificate after two years from the date of adoption of the final rule. After the two-year period, only an FAA-issued plastic pilot certificate may be used to exercise piloting privileges. The proposal would not revoke or otherwise cancel a paper certificate. It would simply require the pilot to have the plastic certificate to exercise the attendant privileges.

We believe that two years is a reasonable time to allow for the replacement of pilot certificates by those who want to act as a pilot after the two-

year period without interruption. (A person may apply for a plastic certificate after the two-year period, but he or she would not be able to exercise piloting privileges until he or she obtained the plastic certificate.) We are assuming that applications for the plastic replacement certificate would be evenly spread out through the two-year period. If all pilots waited until close to the end of the two-year period to apply for the replacement certificate, there would undoubtedly be delays in processing and receipt of the new certificate. The two-year period balances our ability to receive and process applications for replacement certificates, to maintain our existing range of services, and to reduce the risk of counterfeiting of paper certificates.

To effect this change, we are proposing to add new 14 CFR 61.19(h), titled, "Duration of pilot certificates." Readers should note that the NPRM would not require a holder of a paper pilot certificate to surrender the certificate when getting the new plastic certificate. The paper certificate would not authorize the holder to exercise piloting privileges, but those who wish to retain it may do so. The fee for replacing an existing paper certificate would be \$2.00. This nominal fee would defray part of the Registry's cost of replacing the approximately 440,000 existing paper pilot certificates. At the same time, the \$2.00 fee would not be an undue burden on individuals. The NPRM would not apply to student pilot certificates or flight instructor certificates. Under existing regulations, these certificates expire 24 calendar months from the month in which they are issued or renewed. See 14 CFR 61.19(b) and (d).

We are also proposing that ground instructors, flight crewmembers other than pilots (regulated under 14 CFR part 63) and airmen other than flight crewmembers (regulated under 14 CFR part 65) who hold paper airmen certificates may not exercise the privileges of the paper certificates after five years from the effective date of the final rule. After the five-year period, only an FAA-issued plastic airmen certificate could be used to exercise these privileges. The proposal would not revoke or otherwise cancel a paper certificate. It would simply require the airman to have the plastic certificate to exercise the attendant privileges.

Although the FAA Drug Enforcement Assistance Act only addressed pilot certificates, we are proposing a parallel change for these other airmen certificates under the FAA's general rulemaking authority. Ground instructors and part 63 and part 65

airmen play an essential role in the functioning of the civil aviation system. We would be remiss if we did not also seek to address any potential problems associated with accurate identification of these airman certificate holders. A mechanic or flight engineer would have access to aircraft and have opportunities to participate in drug smuggling activities, such as concealment of drugs on the aircraft.

To effect these changes, we are proposing to revise existing 14 CFR 61.19(e) and add new 14 CFR 63.15(d) and 65.15(d). As is the case with pilot certificates, replacement of these certificates would cost the holder \$2.00. To make the replacement process as quick and easy as possible, the Registry has recently set up a system that allows a certificate holder to request a replacement certificate using the Internet. Certificate holders may access this system by going to the following address: <https://amsrvs.registry.faa.gov/amsrvs>.

#### Aircraft Registration

Under the FAA's authorizing legislation, a person may operate an aircraft in the United States only when the aircraft is registered under 49 U.S.C. 44103, with three exceptions. One exception allows operation of an aircraft for a reasonable period of time after transfer of ownership until the new owner completes the registration process. See 49 U.S.C. 44101(b)(3).

The current regulations for aircraft registration (14 CFR part 47) require an aircraft seller to fill in the reverse side of the aircraft registration certificate with the name and address of the buyer and return it to the Registry in Oklahoma City. To operate the newly purchased U.S. civil aircraft, the buyer must complete an application for aircraft registration and send it with evidence of ownership, such as a bill of sale, to the Registry (§ 47.31(a)). Once the Registry examines the application and supporting documents for legibility and compliance with part 47, it issues an aircraft registration certificate to the new owner. It typically takes 30 to 40 days to issue an aircraft registration certificate if there are no complications. During this review period (or for up to 90 days), the buyer may operate the aircraft under temporary authority by retaining a duplicate copy of the registration application—the so-called “pink slip.” The buyer must carry the pink slip in the aircraft as evidence of temporary authority to operate the aircraft without a certificate of registration. The buyer can take advantage of this temporary operating authority only after sending the aircraft

registration package to the Registry (§ 47.31(b)). The current requirements, including the ability to operate an aircraft under temporary authority based on the pink slip, were established to provide a smooth transfer of ownership that would not unduly restrict operation of the aircraft during processing of an application for registration.

The Act authorizes the FAA to modify the system for registering and recording conveyances to make the system more effective in serving the needs of buyers and sellers of aircraft and of officials responsible for enforcement of laws relating to the regulation of controlled substances. See 49 U.S.C. 44111. The Act identified a number of deficiencies and abuses that the modifications must address, including the practice of allowing temporary operation and navigation of aircraft without issuance of a certificate of registration and submission of unidentifiable names of individuals on applications for registration of aircraft. The Act also authorized the FAA to prescribe regulations to address the abuses and deficiencies.

The FAA has taken a number of steps to address the period after sale or transfer of ownership and before application is made for registration. A document index is now available on-line at the Registry Web site (<http://registry.faa.gov>) or through an inquiry to the FAA Law Enforcement Assistance Program. The index, which is updated daily, tells whether the Registry has received documents related to a specific aircraft. The FAA Law Enforcement Assistance Program can retrieve all documents associated with an aircraft in a matter of minutes. If there is any question as to the ownership of an aircraft, the documents can be forwarded to the appropriate law enforcement organization.

If law enforcement personnel are questioning the operator of an aircraft who is using a pink slip, they can check the document index to determine if documents have been received for that aircraft. If no documents are shown in the index, then there is increased likelihood the aircraft is being operated in an unauthorized manner. Also, the entire aircraft registry database is available on-line at the Registry Web site. When an aircraft is sold, the seller must notify the Registry of the sale, and the Registry identifies the aircraft as “sale reported” until it processes the buyer's registration application. The Registry updates this information daily. Anyone can check an aircraft's registration through the Registry Web site to see if the aircraft is identified as “sale reported.” The Registry contains

over 25 million pages of aircraft information in digital format.

Our current regulations at 14 CFR 47.31(a) require each applicant for aircraft registration to send the registration application to the Registry. Paragraph (b) of the same section allows the applicant to carry the pink slip in the aircraft as temporary authority to operate it *after complying with paragraph (a)*. (Emphasis added.) To use the pink slip as temporary operating authority, the aircraft operator must have already sent the registration application to the Registry. It is not legal to operate the aircraft under a pink slip if the operator has not sent the registration application to the Registry.

In spite of current regulatory requirements and the administrative actions we have taken, as outlined above, we still have a concern about the accuracy of ownership information contained in the Registry. Those who transfer ownership of U.S.-registered aircraft may not be notifying the Registry of the transfer in a timely fashion. The effectiveness of the Registry's document index and aircraft registry database depends on the accuracy and timeliness of the information they contain. If a law enforcement agency investigating an aircraft goes to the index or the database for ownership information, and the information does not reflect a recent transfer of ownership, the investigation may be stymied or delayed. For this reason, we are proposing an amendment to 14 CFR 47.41(b) that would require the person selling, or otherwise transferring ownership of, a U.S.-registered aircraft to return the certificate of aircraft registration to the Registry within five days of sale or transfer.

We believe that five days is a reasonable amount of time to complete the reverse side of the certificate and send it to the Registry. It achieves a balance between our need to have accurate, up-to-date information in the Registry for the use of law enforcement agencies and our desire not to unduly burden individuals. We specifically request comments from the public, particularly owners of U.S.-registered aircraft, concerning whether this is a reasonable time frame.

To address the problem of the submission of illegible names of individuals on applications for registration of aircraft, we are proposing to require each applicant to provide a printed or typed name with his or her signature. The Registry has already included this requirement in the instructions for completing the aircraft registration application. We are

proposing to add it to our regulations to bolster our authority to reject applications that contain illegible names. To effect this change, we are modifying a previously undesignated portion of 14 CFR 47.31 that appears between existing paragraphs (a) and (b). Currently, the FAA rejects an application if it is not completed or if the name and signature on the application are not the same throughout. Under this proposal, the currently undesignated provision would become new 14 CFR 47.31(b) and would include the requirement for a printed or typed name under the signature. Existing paragraphs (b) and (c) would be redesignated as paragraphs (c) and (d).

#### **Paperwork Reduction Act**

This proposal contains the following new information collection requirements. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. § 3507(d)), the FAA has submitted the information requirements associated with this proposal to the Office of Management and Budget for its review.

*Title:* Drug Enforcement Assistance.

*Summary:* Two years after the final rule becomes effective, paper pilot certificates may no longer be used to exercise piloting privileges. Five years after the final rule becomes effective, certain other paper airmen certificates, such as those of flight engineers and mechanics, may no longer be used to exercise the privileges authorized by those certificates. To exercise the privileges after those respective dates, the airmen would have to hold upgraded, counterfeit-resistant plastic certificates.

*Use:* These changes are responsive to concerns raised in the FAA Drug Enforcement Assistance Act. The purpose of the changes is to upgrade the quality of data and documents to assist Federal, State, and local agencies to enforce the Nation's drug laws.

*Respondents (including number of):* The FAA estimates that there are 900,000 active airmen, of which 450,000 are pilots.

*Frequency:* This is a one-time requirement.

*Annual Burden Estimate:* Each airman having a paper certificate would need to provide the FAA, the Airmen Certification Branch at the Civil Aviation Registry, with the appropriate paperwork. This can be done either through the mail or electronically. The fee for this new replacement certificate is \$2. The FAA assumes that it will take no more than five minutes for each airman to process the paperwork; the total cost to each airman would be about

\$3. Five-year costs range from \$2.80 million (\$2.42 million, discounted) to \$4.43 million (\$3.82 million, discounted).

The agency is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Individuals and organizations may submit comments on the information collection requirement by March 6, 2007, and should direct them to the address listed in the **ADDRESSES** section of this document. Comments also should be submitted to the Office of Information and Regulatory Affairs, OMB, New Executive Building, Room 10202, 725 17th Street, NW., Washington, DC 20053, Attention: Desk Officer for FAA.

According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid OMB control number. The OMB control number for this information collection will be published in the **Federal Register**, after the Office of Management and Budget approves it.

#### **International Compatibility**

In keeping with U.S. obligations under the Convention on International Civil Aviation, FAA's policy is to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA determined that there are no ICAO Standards and Recommended Practices that correspond to these proposed regulations.

#### **Economic Summary**

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs 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 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (19 U.S.C. 2531–2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, to be the basis of U.S. standards. Fourth, 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). The FAA currently uses an inflation-adjusted value of \$128.1 million in lieu of \$100 million.

In conducting these analyses, FAA has determined this rule: (1) Has benefits that justify its costs, is not a “significant regulatory action” as defined in section 3(f) of Executive Order 12866, but is “significant” under DOT's Regulatory Policies and Procedures; (2) will not have a significant economic impact on a substantial number of small entities; (3) will not affect international trade; and does not impose an unfunded mandate on state, local, or tribal governments, or on the private sector. These analyses, available in the docket, are summarized below.

#### **Total Costs and Benefits of This Rulemaking**

Total estimated costs, over five years, to replace paper certificates with plastic, range from a low of \$3.73 million (\$3.22 million, discounted) to \$5.91 million (\$5.09 million, discounted). These are the estimated costs that the rule would impose on the government and the private sector by requiring replacement of paper certificates with plastic.

Reliable data is not available upon which to quantify benefits. However, this proposed rule is mandated by statute; consequently, the American people, through their elected officials, have established that the benefits justify the costs.

#### **Who Is Potentially Affected by This Rulemaking**

##### *Private Sector*

All airmen who currently have paper certificates that want to continue to be able to exercise those privileges.

### Government

The Civil Aviation Registry would need to process an estimated 545,900 to 863,900 certificates because of the rule.

### Our Cost Assumptions and Sources of Information

- Discount rate—7%;
- Period of analysis—2006 through 2010;
- All monetary values are expressed in 2005 dollars;
- There are currently 900,135 paper certificates for airmen—of these, almost 450,000 are pilots, while the balance are other airmen; all but those that would normally be issued for replacement and additional ratings without the proposed rule and those that are currently held by certified flight instructors (CFI) would need to be replaced by the rule.
- By the start of 2006 the FAA estimates that the number of paper certificates would be reduced to 863,859 because pilots and airmen are currently being issued plastic certificates due to replacements and additional ratings.
- The FAA assumes that an equal number of certificates would be replaced each year. For pilots, approximately 208,700 would be replaced in each of the first two years, and for all other airmen, approximately 89,300 would be replaced each year;
- The FAA considered a low cost and high cost scenario.
- The time for an airman to fill out the Pilot Certificate Reissuance Form is five minutes. The FAA believes that the actual amount of time is probably less than this, but is using five minutes uniformly so as to be conservative and not underestimate costs;
- Airman's time is costed out at \$37.76 per hour;
- An FG-10 time is costed out at \$33.09 per hour; and
- An FG-6 time is costed out at \$22.11 per hour.

### Low Cost Scenario Assumptions

- Not all replacements can be attributed to the rule.
- The FAA assumes that approximately 56,200 airmen certificates would be replaced each year without the rule.
- In addition, the FAA assumes that approximately 48,000 certificates would be issued annually for additional ratings on an existing certificate.
- 65% of both the replacement and new certificates issued for additional ratings are for pilots.
- Without the rule, each year approximately 36,500 pilot certificates would be replaced and approximately 31,200 pilot certificates would be issued

for additional ratings. Of the approximately 208,700 pilot certificates that must be replaced, approximately 67,800 would be replaced without the rule and therefore approximately 140,900 would have to be replaced because of the rule in each of the first two years.

- 35% of both the replacement and new certificates issued for additional ratings are for other airmen.
- Without the rule, each year approximately 19,700 other airmen certificates would be replaced and approximately 16,800 other airmen certificates would be issued for additional ratings. Of the approximately 89,300 other airmen certificates that would be replaced each year, approximately 36,500 would be replaced without the rule and approximately 52,800 would have to be replaced because of the rule in each of the first five years.

### High Cost Scenario Assumption

- Assumes that airmen would not replace or upgrade paper certificates without the rule.

### Benefits of This Rulemaking

Congress has determined that, at the present time, the smuggling of drugs into the United States by general aviation aircraft is a major contributing factor in the illegal drug crisis facing the nation. As a result of that determination, the Congress expanded the mission of the FAA to include assisting law enforcement agencies in the enforcement of laws regulating controlled substances, to the extent consistent with aviation safety.

The Congress has stated in the Drug-Free America Policy of the Drug Enforcement Assistance Act of 1988 that the total cost of drug use to the economy is estimated to be over \$100 billion annually. Were this rule to reduce society's economic cost of drug use by approximately 1/85,000th for the high cost scenario or 1/134,000th for the low cost scenario over five years, that achievement would approximately equal the estimated cost to society of these regulatory changes. The FAA believes that such a reduction is achievable. Congress, which reflects the will of the American public, has determined that this proposed action is in the best interest of the nation.

### Costs of This Rulemaking

The FAA assumes that an equal number of paper airmen certificates will be replaced each year. The FAA projects that there will be about 417,300 pilots who will still hold paper certificates at the start of 2006, so the FAA assumes

that about 208,700 would get their new plastic certificate in 2006 and in 2007. Excluding the CFI's, about 446,500 other individuals with airman certificates would need to replace their certificates over a 5 year period, or about 89,300 a year.

The FAA has considered two cost scenarios. The first low cost scenario assumes that, since some airmen have been replacing their paper certificates with the new plastic certificates either because they have requested replacement certificates or because they have received new certificates after attaining additional ratings, they would continue to do so without the rule. The cost that these pilots would incur to replace their certificates cannot be considered a cost of the proposed rule, since they would replace their certificates without the rule. The second high cost scenario assumes that no pilots or airmen would replace their paper certificates with plastic certificates unless the rule required them to do so.

### Low Cost Scenario

In this scenario, we assume that without the rule, approximately 36,500 pilots and about 19,700 other airmen would replace their certificates annually. Further, some airmen acquire a new certificate because they earn additional ratings. We estimate that approximately 31,200 pilots and about 16,800 other airmen would earn additional ratings annually and be issued a new plastic certificate to reflect these additional ratings. Since this would occur regardless of the proposed rule, the cost to replace these certificates would not be considered a cost of the rule.

To summarize, approximately 67,800 pilots would acquire plastic certificates annually regardless of the proposed rule. In each of the first two years, approximately 140,900 pilots would have to replace their certificates because of the proposed rule (208,700 minus 68,000). In addition, approximately 36,500 other airmen would acquire plastic certificates annually regardless of the proposed rule. In each of the first five years, approximately 52,800 other airmen would have to replace their certificates because of the proposed rule (89,300 minus 36,500). This scenario may underestimate costs because it assumes that replacements and upgrades that would occur regardless of the proposed rule would always replace paper certificates. However, once paper certificates become replaced with plastic, some of the later replacements/upgrades not related to the rule, would

involve replacement/upgrades of plastic certificates.

### High Cost Scenario

In this scenario the FAA assumes that there would be no replacements or upgrades without the rule and that the cost of the proposed rule would be the cost to replace all paper certificates that exist as of the start of 2006 (which is when we assume the rule will take effect). Therefore, the FAA assumes that in each of the first two years, approximately 208,700 pilots would have to replace their paper certificates with plastic, and that these costs are attributed completely to the proposed rule. The FAA also assumes that in each of the first five years, approximately 89,300 other airmen would have to replace their paper certificates with plastic because of the proposed rule. This is an extremely conservative scenario, which overestimates cost.

### Costs

There are two sets of costs associated with replacing the current paper certificates, one for airmen and one for the Government.

#### *Airmen Costs*

Each airman having a paper certificate would need to provide the FAA, the Airmen Certification Branch at the Civil Aviation Registry with the appropriate paperwork. This can be done either through the mail or electronically. The fee for this new replacement certificate is \$2. The FAA assumes that it will take no more than five minutes for each airman to process the paperwork; the total cost to each airman would be about \$3. Five-year costs range from \$2.87 million (\$2.47 million, discounted) to \$4.54 million (\$3.90 million, discounted). The lower cost represents the low cost scenario; the higher cost represents the high cost scenario.

#### *Government Costs*

There are several steps involved with the FAA processing a request for a duplicate airman certificate. These steps include different grade levels and/or contract costs and includes Legal Instruments Examiners as well as contractors who would preprocess and scan the images, index the image, review the certificate for accuracy, and print and mail the certificates. The total costs per new certificate sum to \$3.59. However, airmen would pay \$2 for the certificate and therefore the net cost to the government would be \$1.59 per certificate; five-year costs range from \$867,900 (\$749,300, discounted) to \$1.37 million (\$1.18 million discounted). The lower cost represents

the low cost scenario; the higher cost represents the high cost scenario.

Total costs, over five years, to replace the existing paper certificates range from \$3.73 million (\$3.22 million, discounted) to \$5.91 million (\$5.09 million, discounted). The lower cost represents the low cost scenario; the higher cost represents the high cost scenario.

### Initial 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.

However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the 1980 RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This rule affects aircraft owners, through part 47, and pilots, through parts 61, 63, and 65.

The change to part 47 would affect all aircraft owners. However, as stated above, they have always been required to send in the registration package upon purchase of a new aircraft; this proposal does not impose any new requirements on new aircraft owners. Accordingly, there are no additional costs for these owners.

The changes to parts 61, 63, and 65 would impose an estimated \$5 in compliance costs on pilots applying for certificate reissuances. This cost covers the costs for the postage, applicant's time, and the \$2 reissuance fee charged to pilots. However, pilots are not small

entities and are not covered by the Regulatory Flexibility Act. The FAA recognizes that there are one-man businesses that provide aviation services; however, the cost of this proposed rule to them would be negligible and, therefore, not significant.

Thus, the FAA certifies that this proposal would not have a significant economic impact on a substantial number of small entities.

### International Trade Impact Assessment

The Trade Agreement Act of 1979 prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. 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 NPRM and has determined that it would have only a domestic impact and therefore no affect on any trade-sensitive activity.

### Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (the Act) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act 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 (adjusted annually for inflation) 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 \$128.1 million in lieu of \$100 million.

This proposed rule does not contain such a mandate. The requirements of Title II do not apply.

### Executive Order 13132, Federalism

The FAA has analyzed this NPRM 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 national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, we determined that this NPRM does not have federalism implications.



## Plain English

Executive Order 12866 (58 FR 51735, Oct. 4, 1993) requires each agency to write regulations that are simple and easy to understand. We invite your comments on how to make these regulations easier to understand, including answers to questions such as the following:

- Are the requirements in the regulations clearly stated?
- Do the regulations contain technical language or jargon that interferes with their clarity?
- Would the regulations be easier to understand if they were divided into more (but shorter) sections?
- Is the description in the preamble helpful in understanding the regulations?

Please send your comments to the address specified in the **ADDRESSES** section.

## 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 proposed 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 has analyzed this NPRM under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 18, 2001). We have determined that it is not a “significant energy action” under the executive order because it is not a “significant regulatory action” under Executive Order 12866, and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

## List of Subjects

### 14 CFR Part 47

Aircraft, Reporting and recordkeeping requirements.

### 14 CFR Part 61

Aircraft, Airmen, Alcohol abuse, Drug abuse, Recreation and recreation areas, Reporting and recordkeeping requirements, Teachers.

### 14 CFR Part 63

Aircraft, Airmen, Alcohol abuse, Drug abuse, Navigation (air), Reporting and recordkeeping requirements.

### 14 CFR Part 65

Air traffic controllers, Aircraft, Airmen, Airports, Alcohol abuse, Drug abuse, Reporting and recordkeeping requirements.

## The Proposed Amendments

In consideration of the foregoing the Federal Aviation Administration proposes to amend Chapter I of Title 14 Code of Federal Regulations as follows:

## PART 47—AIRCRAFT REGISTRATION

1. The authority citation for part 47 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113–40114, 44101–44108, 44110–44111, 44703–44704, 44713, 45302, 46104, 46301; 4 U.S.T. 1830.

2. Redesignate existing paragraphs (b) and (c) as (c) and (d) and the undesignated text following paragraph (a)(3) is designated as a new paragraph (b) and revised to read as follows:

### § 47.31 Application.

\* \* \* \* \*

(b) The FAA rejects an application when—

- (1) Any form is not completed;
- (2) The name and signature of the applicant are not the same throughout; or

(3) The applicant does not provide a legibly printed or typed name with the signature in the signature block.

\* \* \* \* \*

3. Amend § 47.41 by revising paragraph (b) to read as follows:

### § 47.41 Duration and return of Certificate.

\* \* \* \* \*

(b) The Certificate of Aircraft Registration, with the reverse side completed, must be returned to the FAA Aircraft Registry—

(1) Within 5 days in the case of registration under the laws of a foreign country, by the person who was the owner of the aircraft before foreign registration;

(2) Within 60 days after the death of the holder of the certificate, by the administrator or executor of his estate, or by his heir-at-law if no administrator or executor has been or is to be appointed; or

(3) Within 5 days of the termination of the registration, by the holder of the Certificate of Aircraft Registration in all other cases mentioned in paragraph (a) of this section.

## PART 61—CERTIFICATION: PILOTS, FLIGHT INSTRUCTORS, AND GROUND INSTRUCTORS

4. The authority citation for part 61 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701–44703, 44707, 44709–44711, 45102–45103, 45301–45302.

5. Amend § 61.19 by:
  - A. Revising paragraph (e); and
  - B. By adding new paragraph (h) to read as follows:

### § 61.19 Duration of pilot and instructor certificates.

\* \* \* \* \*

(e) *Ground instructor certificate.*

(1) A ground instructor certificate issued under this part is issued without a specific expiration date.

(2) The holder of a paper certificate issued under this part may not exercise the privileges of that certificate after [DATE 5 YEARS AND 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

\* \* \* \* \*

(h) *Duration of pilot certificates.* The holder of a paper certificate issued under this part may not exercise the privileges of that certificate after [DATE 2 YEARS AND 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

## PART 63—CERTIFICATION: FLIGHT CREWMEMBERS OTHER THAN PILOTS

6. The authority citation for part 63 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701–44703, 44707, 44709–44711, 45102–45103, 45301–45302.

7. Amend § 63.15 by adding new paragraph (d) to read as follows:

### § 63.15 Duration of certificates.

\* \* \* \* \*

(d) The holder of a paper certificate issued under this part may not exercise the privileges of that certificate after [DATE 5 YEARS AND 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

## PART 65—CERTIFICATION: AIRMEN OTHER THAN FLIGHT CREWMEMBERS

8. The authority citation for part 65 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701–44703, 44707, 44709–44711, 45102–45103, 45301–45302.

9. Amend § 65.15 by adding new paragraph (d) to read as follows:

### § 65.15 Duration of certificates.

\* \* \* \* \*

(d) The holder of a paper certificate issued under this part may not exercise the privileges of that certificate after [DATE 5 YEARS AND 30 DAYS FROM



DATE OF PUBLICATION IN THE  
FEDERAL REGISTER].

Issued in Washington, DC, on December 27, 2006.

James Ballough,

Director, Flight Standards Service.

[FR Doc. 06-9989 Filed 1-4-07; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND  
HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 101

[Docket No. 2004P-0464]

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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend the regulation authorizing a health claim on the relationship between calcium and a reduced risk of osteoporosis to: Include vitamin D so that, in addition to claims for calcium and osteoporosis, additional claims can be made for calcium and vitamin D and osteoporosis; eliminate the requirement in § 101.72(c)(2)(i)(A) (21 CFR 101.72(c)(2)(i)(A)) that the claim list sex, race, and age as specific risk factors for the development of osteoporosis; eliminate the requirement in § 101.72(c)(2)(i)(B) that the claim does not state or imply that the risk of osteoporosis is equally applicable to the general U.S. population, and that the claim identify the populations at particular risk for the development of osteoporosis; eliminate the requirement in § 101.72(c)(2)(i)(C) that the claim identify the mechanism by which calcium reduces the risk of osteoporosis and instead make it optional; and eliminate the requirement in § 101.72(c)(2)(i)(E) that the claim include a statement that reflects the limit of the benefits derived from dietary calcium intake, when the level of calcium in the food exceeds a set threshold level. FDA is taking these actions, in part, in response to a health claim petition submitted by The Beverage Institute for Health and Wellness, LLC. Elsewhere in this issue of the **Federal Register**, FDA is withdrawing certain proposed amendments to a proposed rule that published in the **Federal Register** of December 21, 1995 (60 FR 66206)

related to the calcium and osteoporosis health claim.

**DATES:** Submit written or electronic comments by March 21, 2007.

**ADDRESSES:** You may submit comments, identified by Docket No. 2004P-0464, by any of the following methods:

*Electronic Submissions*

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>.

Follow the instructions for submitting comments on the agency Web site.

*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 in the *Electronic Submissions* portion of this paragraph.

**Instructions:** All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, 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.fda.gov/ohrms/dockets/default.htm> 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.

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

**SUPPLEMENTARY INFORMATION:****Table of Contents**

- I. Background
- II. Petition and Grounds for Amending the Health Claim on Calcium and Osteoporosis
  - A. The Petition
  - B. Nature of the Substance
- III. Review of Scientific Evidence of the Substance-Disease Relationship
  - A. Basis for Evaluating the Relationship between Calcium and Vitamin D and Osteoporosis
  - B. Review of the Scientific Evidence of the Substance-Disease Relationship
- IV. Decision to Amend the Calcium and Osteoporosis Health Claim
  - A. Addition of Vitamin D
  - B. Amendments to the Calcium and Osteoporosis Health Claim Other than the Inclusion of Vitamin D
  - C. Elimination of the Requirement to List Race, Age and Sex as Risk Factors for the Development of Osteoporosis
  - D. Elimination of the Requirement that the Claim Not State or Imply that the Risk of Osteoporosis is Equally Applicable to the General Population, and that the Claim Identify the Populations at Particular Risk for the Development of Osteoporosis
  - E. Elimination of the Requirement that the Claim Identify the Mechanism by Which Calcium Reduces the Risk of Osteoporosis
  - F. Elimination of the Requirement in § 101.72(c)(2)(i)(E) that Certain Products Bearing the Claim Include a Statement that Reflects the Limits on the Benefits from Calcium
- V. Description of Modifications to § 101.72
  - A. Title of the Regulation
  - B. General Requirements
- VI. Analysis of Economic Impacts
  - A. Preliminary Regulatory Impact Analysis
  - B. Small Entity Analysis (or Initial Regulatory Flexibility Analysis)
- VII. Environmental Impact
- VIII. Paperwork Reduction Act
- IX. Federalism
- X. Comments
- XI. References

**I. Background**

The Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101-535) amended the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. The NLEA clarified FDA's authority to regulate health claims on food labels and in food labeling by amending the act to add section 403(r) to the act (21 U.S.C. 343(r)). Section 403(r) specifies, in part,