

procedures and calculations prescribed by the 2015 amendments and OMB's guidance, the Board adjusted the maximum level of each of the CMPs that NCUA has authority to assess. NCUA is not, however, required to assess at the new maximum levels and retains discretion to assess at lower levels, as it has done historically.⁸

The interim final rule became effective on July 21, 2016. The Board received no comments on the rule.

B. Prospective Effect of Adjustments

Although the Board received no comments on the interim final rule, it wishes to clarify its intended use of adjusted maximums for violations that occurred prior to the adjustment. As described in the interim final rule, the 2015 amendments provide that increased maximum CMP amounts apply to penalties assessed after the adjustments take effect, including those for which the associated violation occurred before the adjustment became effective.⁹ The Board adopted this provision in the interim final rule consistent with the statute.¹⁰

The Board has observed that agencies have appeared to vary in their adoption of this provision. Some agencies' interim final rules provide that the adjusted maximums apply only to violations occurring after November 2, 2015, when the 2015 amendments became law.¹¹ Other agencies' rules, like the NCUA's interim final rule, do not specify whether the adjusted maximums would apply to violations that occurred before the 2015 amendments were enacted.¹² To avoid confusion, the Board clarifies that it interprets the 2015 amendments as applying only prospectively. If NCUA assesses CMPs at the maximum level, it would not apply the new maximums to violations that occurred before the statute was amended on November 2, 2015. As noted above, nothing in the 2015 amendments or the final rule requires application of maximum-level CMPs. Further, as explained in the interim final rule, NCUA generally must consider mitigating factors, including financial resources, in assessing a CMP.¹³

Apart from this clarification, the Board adopts the interim final rule as final without changes.

II. Regulatory Procedures

Section III of the Supplementary Information in the June 2016 interim final rule sets forth the Board's analyses under the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act of 1995, the Small Business Enforcement Fairness Act, Executive Order 13132, and the Treasury and General Government Appropriations Act. See 81 FR 40156–40157. Because the final rule confirms the interim final rule and does not alter the substance of the analyses and determinations accompanying the interim final rule, the Board continues to rely on those analyses and determinations for purposes of this rulemaking. The Board notes that OMB determined that the interim final rule is not a “major rule” within the meaning of the Small Business Enforcement Fairness Act.

List of Subjects in 12 CFR Part 747

Credit unions, Civil monetary penalties.

By the National Credit Union Administration Board on October 27, 2016.

Gerard S. Poliquin,
Secretary of the Board.

For the reasons stated above, the interim final rule amending 12 CFR part 747, published at 81 FR 40152 (June 21, 2016), is adopted as a final rule without change.

[FR Doc. 2016–26712 Filed 11–4–16; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2015–2776; Aerospace Docket No. 15–AEA–5]

RIN 2120-AA66

Amendment and Establishment of Restricted Areas; Chincoteague Inlet, VA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action expands the restricted airspace at Chincoteague Inlet, VA, to support the National Aeronautics and Space Administration's (NASA) Wallops Island Flight Facility (WFF) test requirements. This action adds 3

new restricted areas, designated R–6604C, R–6604D, and R–6604E. Additionally, a minor change is made to 2 points in the boundary of existing area R–6604A to match the updated 3-nautical mile (NM) line from the shoreline of the United States (U.S.) as provided by the National Oceanic and Atmospheric Administration (NOAA).

DATES: Effective date 0901 UTC, January 5, 2017.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it restructures the restricted airspace at Chincoteague Inlet, VA to enhance aviation safety and accommodate essential NASA testing programs.

History

On September 10, 2015, the FAA published in the **Federal Register** a notice proposing to expand the restricted airspace at Chincoteague Inlet, VA, to support NASA's WFF test requirements (80 FR 54444), Docket No. FAA–2015–2776. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. Due to an error, a chart depicting the proposed areas was not posted to the regulations.gov Web site for public viewing until November 5, 2015 (10 days after the close of the comment period). Consequently, on January 21, 2016, the FAA published a notice reopening the comment period for 30 additional days (81 FR 3353), Docket No. FAA–2015–2776, to provide the public the opportunity to view the chart and submit comments.

Discussion of Comments

A total of 17 comments were received, including 2 duplicate submissions.

⁸ 81 FR 40152, 40156 (June 21, 2016).

⁹ Public Law 114–74, 129 Stat. 600 (Nov. 2, 2015), codified at 28 U.S.C. 2461 note.

¹⁰ 81 FR 40152, 40156 (June 21, 2016).

¹¹ See, e.g., Dep't of Justice, Civil Monetary Penalties Inflation Adjustment, 81 FR 42491, 42499 (June 30, 2106).

¹² See, e.g., Dep't of Defense, Civil Monetary Penalty Inflation Adjustment, 81 FR 33389, 33390 (May 26, 2016).

¹³ 81 FR 40152, 40156 (June 21, 2016).

Eight commenters expressed support for the proposal. Several of the supporters wrote that restricted areas R-6604D and R-6604E abut, but do not include, VOR Federal airway V-139, concluding, when those areas are in use, air traffic can continue to flow unimpeded on the airway.

FAA Response. VOR Federal airways, such as V-139 consist of that airspace within 4-NM either side of the airway centerline. R-6604D and R-6604E essentially abut the centerline of V-139, which means they infringe upon the 4-NM width on the east side of the airway centerline. Therefore, the airway would be unusable below 4,000 feet MSL when either R-6604D or R-6604E is active. When the restricted areas are active, instrument flight rules (IFR) traffic must use the airway at or above 4,000 feet MSL. Otherwise, they must be vectored to remain clear of the active restricted areas or navigate by other airways. As an alternative, pilots flying northeast-bound could use V-1 or V-139 to the Cape Charles VORTAC (CCV), VA, then fly V-1 to the Waterloo VOR/DME (ATR), DE, then V-308 to the Sea Isle VORTAC (SIE), NJ, then rejoin V-139. This alternative would only add about 2-NM to the route of flight. Conversely, southwest-bound traffic could fly V-139 to the Sea Isle VORTAC, then follow the reverse of the routing shown above and rejoin V-139 at the Cape Charles VORTAC. Air Traffic Control (ATC) will ensure IFR traffic filed via V-139 is separated from active restricted airspace by means of altitude assignment, route clearance, or radar vectors.

VFR pilots who elect to navigate via V-139 would have to fly above the restricted areas at the appropriate VFR cruising altitude for the direction of flight. VFR cruising altitudes are "odd thousands plus 500 feet for northeast-bound traffic and even thousands plus 500 feet for southwest-bound traffic. Therefore, for VFR traffic navigating on V-139 (when the restricted areas are active), the lowest available altitudes would be 5,500 feet MSL for northeast-bound traffic; and 4,500 feet MSL for southwest-bound traffic. VFR aircraft may also elect to deviate around the restricted airspace or use the alternate routing described above. ATC will continue to provide VFR flight advisories throughout the airspace on a workload permitting basis. When the restricted areas are not active, V-139 is fully available for air traffic. These restricted areas are expected to receive limited usage on an annual basis.

Seven commenters stated additional concerns about the proposal, which are discussed below.

The Aircraft Owners and Pilots Association (AOPA) wrote that the published feeder route from the Snow Hill VORTAC to the GOBYO initial approach fix, serving the GPS approach to runway 32 at Ocean City Municipal Airport, MD, (KOXB), would be unavailable during the time R-6604D is activated. This would reduce the efficiency provided by the feeder route increasing the likelihood of pilots flying longer distances with increased fuel consumption and costs to the operator.

FAA Response. ATC will offset this impact by either clearing the aircraft to GOBYO at 4,000 feet MSL or above, or vectoring the aircraft a short distance around the restricted areas.

AOPA noted that the need to circumnavigate the restricted areas, when active, would also affect pilots operating under VFR. When active, the new restricted areas would render as unavailable key VFR landmarks, such as U.S. Route 13, railroad tracks and the seashore, that are used by VFR pilots who navigate without GPS or navigation aids and who fly at lower altitudes. AOPA said that avoiding the restricted areas by flying to the east, over open water, would be dangerous for single-engine, shoreline-following pilots, and it would be time consuming for those diverting around the complex to the west. AOPA requested that stand-alone VFR waypoints be charted in the Chincoteague area to assist pilots unfamiliar with the area to safely navigate around the restricted areas.

The FAA agrees and will develop charted VFR waypoints to assist VFR aircraft in avoiding the restricted areas. When the restricted areas are not in use, the above mentioned landmarks would remain available for VFR navigation.

AOPA advised that, since the new restricted areas are close to numerous final approach courses of surrounding airports, they must be depicted on applicable Instrument Approach Procedure Charts to increase pilot awareness.

The FAA agrees and is taking action to depict the new restricted areas on applicable instrument procedure charts.

AOPA noted that the proposed restricted areas would be activated "By NOTAM," but the NPRM did not indicate how far in advance the NOTAM should be issued. AOPA recommended at least 12 hours notice is necessary to assist pilots in flight planning.

NASA agreed to revise the time of designation for R-6604C, D and E to read "By NOTAM at least 12 hours in advance."

The Helicopter Association International (HAI) wrote that it was

unable to support the proposed changes. HAI said that the restricted area expansion would impact both IFR and VFR operators. Helicopter operators would be required to either fly further offshore for longer periods to circumnavigate the area, or fly further west into a more tightly congested corridor. HAI is concerned with the offshore option, especially during winter when lower sea temperatures would greatly reduce aircrew survivability times if an emergency resulted in a water entry. Further, the increased minimum altitudes to overfly R-6604D and R-6604E could force helicopter operators higher and subject them to increased encounters with icing conditions.

FAA Response. Helicopter operators would have the option to avoid the restricted areas via the alternate routing discussed above or by use of the VFR waypoints being developed for that purpose. Additionally, the limited projected annual use of the areas described previously should lessen the potential impacts on helicopter operations. Further, NASA has agreed to promptly release the restricted areas to ATC for active medevac or search and rescue helicopter operations.

One commenter contended that a requirement for restricted airspace was not established and suggested the use of a less restrictive type of special use airspace (SUA) such as a warning area. The commenter believes that the proposal did not justify why SUA must be established over land for this purpose and that establishing test airspace over water adjacent to Wallops should be considered before establishing SUA over land.

FAA Response. NASA proposed the restricted area expansion to accommodate a variety of test activities that pose a hazard to nonparticipating aircraft. These activities include, but are not limited to, high-risk test profiles by heavily modified test aircraft, testing of emitters that could induce harmful electromagnetic interference effects on nonparticipating aircraft, non-eye-safe laser firings, and external stores separation testing. Warning areas may also contain hazardous activities and they are established offshore. However, while warning areas serve notice of the possible existence of hazardous activities, they do not restrict access by nonparticipating aircraft that elect to transit the airspace. There is an existing warning area, W-386, located offshore near WFF, but this area is delegated to the U.S. Navy which has its own requirements and scheduling priorities. NASA does use the overwater SUA to the extent possible, but some test

operations require overland airspace in close proximity to an airfield. NASA's restricted area proposal was designed for this specific purpose.

During the design of the proposal, other types of SUA were considered but deemed insufficient for ensuring safety during NASA's flight test operations. Use of nearby existing restricted areas were not an option due to technical requirements (co-use airspace versus exclusive-use airspace; travel distance to the SUA) as well as the dynamic nature of NASA's flight test program. For example, the vast majority of the Patuxent River Naval Air Station's restricted areas are not exclusive use. The parts of the Patuxent River restricted area complex that could be scheduled as exclusive use are in high demand and used for priority Department of Defense requirements. It would be highly unlikely that NASA would be granted access to this airspace, especially given the dynamic operations schedule.

In this case, the FAA has determined that the restricted area expansion is the appropriate SUA designation to contain NASA's hazardous activities in order to ensure segregation of those activities from nonparticipating aircraft.

Several commenters pointed out that this is very busy airspace used by commercial and private flights. They contended that there is sufficient airspace for testing in other parts of the country.

FAA Response. NASA operates a wide variety of highly modified aircraft at WFF in support of various test missions. The configuration of each aircraft changes often as dictated by the specific test program and the engineering and physical modification work that takes place at WFF. Further, in addition to facilities supporting aircraft operations, the infrastructure in place at WFF includes the communications, telemetry, radar tracking, and flight path guidance necessary to fulfill NASA's testing commitments. It would be impractical and not cost effective to relocate infrastructure and testing operations to another location. In addition, at other locations, NASA testing would be competing for access to airspace and that would adversely impact NASA test programs. The design and projected use of the expanded restricted areas should minimize the impacts on other users of the National Airspace System.

One commenter expressed concern about pilots being able to reliably and quickly determine the activity status of the restricted areas from air traffic control.

FAA Response. In the NPRM, Patuxent River Approach Control was proposed as the controlling agency for R-6604C, D and E. The FAA has since decided that Washington ARTCC, which is the controlling agency for the existing R-6604A and B, should also be the controlling agency for the new restricted areas. The controlling agency typically coordinates SUA status with the using agency and is the primary source for pilots to determine activity status of the airspace at any given time. The "Special Use Airspace Tabulation" on the Washington Sectional Aeronautical Chart currently lists Washington ARTCC as the controlling agency for R-6604A and B. The tabulation also includes area altitudes, time of use and contact frequencies. The tabulation will be updated to include information for R-6604C, D and E. In addition, the requirement that R-6604C, D and E must be activated by a NOTAM issued at least 12 hours in advance should assist pilots in flight planning.

Other Impacts

The FAA identified several other potential impacts. First, when R-6604E is active, it would encroach into the protected airspace for the RNAV (GPS) approach to runway 21 at Accomack County Airport, Melfa, VA, (KMFV). There are several options to address this issue: ATC can provide radar vectors to runway 21; the aircraft could be cleared for the VOR/DME RWY 3 or the LOC RWY 3 approach with a circle to land runway 21; or ATC can temporarily recall a portion of R-6604E to restrict NASA aircraft to a minimum altitude of 2,500 feet MSL or above, allowing aircraft on the approach to fly underneath. Once the traffic on approach is clear, the airspace would be returned to the user. This latter provision would be included in the Letter of Procedure between the FAA and NASA that governs use of the restricted areas.

Second, the protected airspace for the missed approach procedure for the RNAV (GPS) RWY 3 approach at Accomack County Airport would be impacted when R-6604E is active.

FAA plans to amend the missed approach procedure for the RNAV (GPS) RWY 3 approach. In the interim, the VOR/DME RWY 3 approach is available. The missed approach for that procedure does not conflict with the restricted area. Also, as described above, ATC can restrict aircraft operating in R-6604E to a minimum altitude that permits IFR traffic to fly the approach beneath.

Third, Midway Airport (VG56), a private-use airport near Bloxom, VA, would be impacted by the expansion.

Midway is located below R-6604E. The VFR traffic patterns and access to and from the airport would be affected unless operations are coordinated. NASA has agreed to establish a Letter of Agreement with airport operators to minimize impact to the private airports south of the WFF.

Differences From the NPRM

The time of designation for R-6604C, D and E was proposed in the NPRM as "By NOTAM." In response to comments received, the time of designation is changed to read "By NOTAM at least 12 hours in advance."

The controlling agency for R-6604C, D and E was proposed as Patuxent River Approach Control. The FAA determined that Washington ARTCC will be the controlling agency for all R-6604 subareas (A through E).

The Rule

The FAA is amending 14 CFR part 73 by establishing 3 new restricted areas, designated R-6604C, R-6604D and R-6604E, at NASA's WFF in Virginia. The new areas abut the existing restricted areas (R-6604A and R-6604B) and will be used to contain a variety of test activities deemed to pose a hazard to nonparticipating aircraft. The following is a general description of the areas.

R-6604C overlies the WFF airfield and is contained entirely within the WFF property boundary. It extends from the surface up to 3,500 feet mean sea level (MSL). Expected usage will be approximately 1.5 hours per day (in 45-minute periods) on approximately 120 days per year, totaling approximately 180 hours per year.

R-6604D extends from 100 feet above ground level (AGL) up to 3,500 feet MSL. It is located between the western boundary of R-6604B and the centerline of VOR Federal airway V-139, extending approximately 15-NM to the northeast of the R-6604A/R-6604B northern boundary. Expected usage will also be approximately 1.5 hours per day (in 45-minute periods) on approximately 120 days per year, totaling approximately 180 hours per year.

R-6604E extends from 700 feet AGL up to 3,500 feet MSL. It is located between the western boundaries of R-6604A and R-6604B and the centerline of VOR Federal airway V-139. Expected usage will be approximately 1.5 hours per day (in 45-minute periods) on approximately 40 days per year, totaling approximately 60 hours per year.

All 3 areas would be activated by a Notice to Airmen (NOTAM) to be issued at least 12 hours in advance. Specific times of designation were not assigned

for R-6604C, D and E due to the variable nature of test programs.

In addition to the above, 2 points in the boundary of R-6604A that intersect a line 3-NM from the shoreline of the U.S. are adjusted to reflect NOAA's updated calculation of the U.S. shoreline. The rest of the R-6604A description is unchanged.

The configuration of the restricted areas was designed to allow for activation of only that portion of the complex required for the specific test profile being conducted. As is the current practice with R-6604A and R-6604B, when the new restricted areas are not required by the using agency, the airspace will be returned to the controlling agency for access by other aviation users.

Note that the existing areas (R-6604A and R-6604B) will continue to be used, as in the past, for missile and rocket launches, aircraft systems development, expendable launch vehicles, lasers, RPV, and other test programs.

The FAA is taking this action because the existing restricted airspace is too small to fully contain hazardous test profiles conducted by NASA's WFF.

Operational Note: Considering their location, it is important that the new areas be depicted on both the IFR en route chart (L-36) and the VFR chart covering the affected area before they are activated for use. Due to aeronautical chart publication cycles, the publication dates for the applicable IFR and VFR charts are not the same. The effective date of this rule is January 5, 2017, to ensure the airspace will also be depicted on the IFR en route chart, which publishes on that date. However, the new areas will not be available for use or activation by NASA until they also appear on the next edition of the Washington Sectional Aeronautical Chart, which publishes on February 2, 2017.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when

promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has conducted an environmental review for this rulemaking in accordance with FAA Order 1050.1F, *Environmental Impacts: Policies and Procedures*, the National Environmental Policy Act, and its implementing regulations at 40 CFR parts 1500–1508. FAA's environmental impact review included an independent evaluation and adoption of NASA's Final Environmental Assessment for the Establishment of Restricted Area Airspace (R-6604C/D/E) at Goddard Space Flight Center, Wallops Flight Facility, Wallops Island, Virginia, dated October 2016 (hereinafter "the FEA"), for which the FAA was a cooperating agency, and which included the environmental analysis of the expanded restricted airspace at Chincoteague Inlet, VA, to support NASA's Wallops Island Flight Facility (WFF) test requirements consisting of the addition of three new restricted areas, designated R-6604C, R-6604D, and R-6604E, and a minor change to two points in the boundary of existing area R-6604A to match the updated 3-nautical mile (NM) line from the shoreline of the U.S. as provided by NOAA, and as described above. Based on its environmental review, the FAA has determined that the action that is the subject of this rule does not present the potential for significant impacts to the human environment. The FAA's Adoption EA and FONSI-ROD are included in the docket for this rulemaking. The FEA is available at https://sites.wff.nasa.gov/code250/Establishment_R-6604CDE_DEA.html.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

- 1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.66 [Amended]

- 2. Section 73.66 is amended as follows:

* * * * *

R-6604A Chincoteague Inlet, VA [Amended]

By removing the current boundaries and inserting the following in its place:

Boundaries. Beginning at lat. 37°55'25" N., long. 75°24'54" W.; to lat. 37°51'31" N., long. 75°17'16" W.; then along a line 3-NM from and parallel to the shoreline to lat. 37°39'20" N., long. 75°31'19" W.; to lat. 37°47'00" N., long. 75°31'18" W.; to lat. 37°51'00" N., long. 75°29'36" W.; to the point of beginning.

R-6604C Chincoteague Inlet, VA [New]

Boundaries. Beginning at lat. 37°56'57" N., long. 75°28'37" W.; to lat. 37°56'54" N., long. 75°26'56" W.; to lat. 37°56'23" N., long. 75°26'46" W.; to lat. 37°56'45" N., long. 75°27'29" W.; to lat. 37°55'15" N., long. 75°28'23" W.; to lat. 37°55'15" N., long. 75°28'39" W.; to lat. 37°56'32" N., long. 75°29'18" W.; to the point of beginning.

Designated altitudes. Surface to 3,500 feet MSL.

Time of designation. By NOTAM at least 12 hours in advance.

Controlling agency. FAA, Washington ARTCC.

Using agency. Chief, Wallops Station, National Aeronautics and Space Administration, Wallops Island, VA.

R-6604D Chincoteague Inlet, VA [New] Boundaries

Beginning at lat. 38°01'42" N., long. 75°29'28" W.; to lat. 38°07'12" N., long. 75°14'48" W.; to lat. 38°04'36" N., long. 75°08'07" W.; thence along a line 3-NM from and parallel to the shoreline to lat. 37°51'31" N., long. 75°17'16" W.; to lat. 37°56'45" N., long. 75°27'29" W.; to lat. 37°53'55" N., long. 75°29'11" W.; to lat. 37°55'40" N., long. 75°33'27" W.; to the point of beginning; excluding R-6604C.

Designated altitudes. 100 feet AGL to 3,500 feet MSL.

Time of designation. By NOTAM at least 12 hours in advance.

Controlling agency. FAA, Washington ARTCC.

Using agency. Chief, Wallops Station, National Aeronautics and Space Administration, Wallops Island, VA.

R-6604E Chincoteague Inlet, VA [New]

Boundaries. Beginning at lat. 37°55'40" N., long. 75°33'27" W.; to lat. 37°53'55" N., long. 75°29'11" W.; to lat. 37°50'24" N., long. 75°31'19" W.; to lat. 37°39'20" N., long. 75°31'19" W.; to lat. 37°38'57" N., long. 75°31'31" W.; to lat. 37°46'55" N., long. 75°39'13" W.; to the point of beginning.

Designated altitudes. 700 feet AGL to 3,500 feet MSL.

Time of designation. By NOTAM at least 12 hours in advance.

Controlling agency. FAA, Washington ARTCC.

Using agency. Chief, Wallops Station, National Aeronautics and Space Administration, Wallops Island, VA.

* * * * *

Issued in Washington, DC on November 1, 2016.

Leslie M. Swann,

Acting Manager, Airspace Policy Group.

[FR Doc. 2016-26760 Filed 11-4-16; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

[Docket No. FDA-2012-N-0222]

Revision of Organization and Conforming Changes to Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to amend the regulations to reflect organization change in the Agency and to make other conforming changes. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

DATES: This rule is effective November 7, 2016.

FOR FURTHER INFORMATION CONTACT: Vanessa Starks, Management Analysis Services Staff, Food and Drug Administration, 11601 Landsdown St., 3WFN—5th Floor, Rm. 05D12, North Bethesda, MD 20857.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this final rule to amend its regulations by updating the organizational information in part 5 (21 CFR part 5).

The portion of this final rule updating the organizational information in part 5, subpart M, is a rule of Agency organization, procedure, or practice. FDA is issuing these provisions as a final rule without publishing a general notice of proposed rulemaking because such notice is not required for rules of Agency organization, procedure, or practice under 5 U.S.C. 553(b)(3)(A). For the conforming changes to the other regulations, the Agency finds good cause under 5 U.S.C. 553(b)(3)(B) to

dispense with prior notice and comment, and good cause under 5 U.S.C. 553(d)(3) to make these conforming changes effective less than 30 days after publication because such notice and comment and delayed effective date are unnecessary and contrary to the public interest. These changes do not result in any substantive change in the regulations.

II. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule simply updates the organizational information, it does not impose any additional costs on industry. Consequently, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

III. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IV. Analysis of Environmental Impact

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

V. Federalism

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

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority of the Commissioner of Food and Drugs, 21 CFR part 5 is revised to read as follows:

PART 5—ORGANIZATION

- 1. The authority citation for part 5 continues to read as follows:

Authority: 5 U.S.C. 552; 21 U.S.C. 301–397.

- 2. Revise § 5.1100 to read as follows:

§ 5.1100 Headquarters.

*Office of the Commissioner.*¹

Office of the Chief Counsel.

Office of the Executive Secretariat.

Freedom of Information Staff.

Dockets Management Staff.

*Office of the Chief Scientist.*¹

Office of Counter-Terrorism and

Emerging Threats.

Office of Scientific Integrity.

Office of Regulatory Science and

Innovation.

Division of Science Innovation and

Critical Path.

Division of Scientific Computing and

Medical Information.

Office of Scientific Professional

Development.

Office of Health Informatics.

¹ Mailing address: 10903 New Hampshire Ave., Silver Spring, MD 20993.