

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 modifies Class E airspace to support the safety and management of IFR operations at Alliance Municipal Airport.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA-2023-0583 in the **Federal Register** (88 FR 22385, April 13, 2023), proposing to modify Class E airspace at Alliance Municipal Airport, Alliance, NE. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Incorporation by Reference

Class E5 airspace area is published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11G, dated August 19, 2022 and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by modifying Class E airspace beginning at 700 feet above the surface at Alliance Municipal Airport, NE. Class E airspace beginning at 700 feet above the surface is expanded to a 7.6-mile radius to fully contain arriving IFR aircraft operating below 1,500 feet above the surface.

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 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 determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures,” paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

- 1. The authority citation for 14 CFR part 71 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.

§ 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above.

* * * * *

ACE NE E5 Alliance, NE [Amended]

Alliance Municipal Airport, NE
(Lat. 42°03′12″ N, long. 102°48′14″ W)

That airspace extending upward from 700 feet above the surface within a 7.6-mile radius of the airport.

* * * * *

Issued in Des Moines, Washington, on August 3, 2023.

B.G. Chew,

Group Manager, Operations Support Group, Western Service Center.

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1310

[CPSC Docket No. 2022–0025]

Ban of Inclined Sleepers for Infants

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Commission is issuing this final rule to codify in its regulations the ban of inclined sleepers for infants pursuant to the Safe Sleep for Babies Act of 2021, which requires that inclined sleepers for infants, regardless of the date of manufacture, shall be considered a banned hazardous product under the Consumer Product Safety Act.

DATES: This rule is effective on September 15, 2023.

FOR FURTHER INFORMATION CONTACT: Will Cusey, Small Business Ombudsman, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7945 or (888) 531–9070; email: sbo@cpsc.gov.

SUPPLEMENTARY INFORMATION: Pursuant to section 2 of the Safe Sleep for Babies Act of 2021 (SSBA), 15 U.S.C. 2057d, the Consumer Product Safety Commission (Commission or CPSC) is issuing this final rule to reflect, in the Code of Federal Regulations, the statutory ban of inclined sleepers for infants that took effect by operation of law on November 12, 2022.

I. Background and Statutory Authority

On May 3, 2022, Congress passed the Safe Sleep for Babies Act of 2021, H.R. 3182, Public Law 117–126, which the President signed on May 16, 2022. Section 2(a) of the SSBA requires that, not later than 180 days after enactment of that law, “inclined sleepers for infants, regardless of the date of manufacture, shall be considered a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057).” 15 U.S.C. 2057d(a). The SSBA defines inclined sleepers for infants as “product[s] with an inclined sleep surface greater than ten degrees that [are] intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old.” 15 U.S.C. 2057d(b). The SSBA went into effect as a ban enforced by the Commission on November 12, 2022, which was the 180th day after its enactment, making it unlawful for any person to sell, offer for sale, manufacture for sale, distribute in

commerce, or import inclined sleepers for infants as of that date. *See* 15 U.S.C. 2068(a)(1).

On July 26, 2022, CPSC published a notice of proposed rulemaking (NPR) stating the Commission's intention to codify in its regulations the language in the SSBA requiring that inclined sleepers for infants be considered a banned hazardous product under section 8 of the Consumer Product Safety Act (CPSA). 87 FR 44309. CPSC requested and received comments from the public on the proposed rule. Specifically, CPSC requested comments regarding the effective date, interpretation of the SSBA language, and whether testing and certification to the ban should be required for sleep products for infants up to 1 year old. CPSC received a total of 67 comments from medical professionals, academic researchers, safety advocates, a children's products design facility, and a trade association for children's products. Those comments are summarized below in Section III.

II. Overview of the Final Rule Banning Inclined Sleepers for Infants

The Commission issues this final rule¹ to codify the ban of inclined sleepers for infants pursuant to the SSBA as proposed, with a clarification in the purpose and scope section of the ban to make clear that the rule prohibits not only the sale of inclined sleepers for infants but also the offer for sale, manufacture for sale, distribution in commerce, or importation into the United States, of these products. The final rule codifies the definition of "inclined sleeper for infants" as a product with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old. The final rule also affirms that, regardless of the date of manufacture, inclined sleepers for infants are banned hazardous products as of November 12, 2022. The final rule is further discussed in the Staff Briefing Package: Ban of Inclined Sleepers for Infants Under the Safe Sleep for Babies Act.²

III. Response to Comments

Of the 67 comments received by CPSC in response to the NPR, 55 were from

¹ The Commission voted 4–0 to publish this final rule. Chair Hoehn-Saric and Commissioners Feldman and Trumka issued statements in connection with their votes.

² Staff Briefing Package: Ban of Inclined Sleepers for Infants Under the Safe Sleep for Babies Act, available at https://www.cpsc.gov/s3fs-public/Draft-Final-Rule-Ban-of-Inclined-Sleepers-for-Infants.pdf?VersionId=t71_9B_J3r1aXJ2Epbm0PabWOWg2k2T7.

medical professionals including doctors, pediatricians, nurses, academic researchers, and infant safety advocates who provided substantially similar comments expressing general support for the proposed rule. The comments are viewable online at www.regulations.gov under docket number CPSC–2022–0025.³

A. Effective Date

Comment A.1: The majority of commenters supported setting an effective date as soon as possible, but not later than the statutory effective date of November 12, 2022. No commenters advocated for a later date.

Response A.1: The SSBA's statutory ban of inclined sleepers for infants went into effect on November 12, 2022, and CPSC has been enforcing it since that time. Accordingly, the final rule will have an effective date 30 days after publication, which is the minimum period provided in the Administrative Procedure Act (APA), 5 U.S.C. 553(d). This effective date for the rule does not change the fact that inclined sleepers for infants have been banned pursuant to the SSBA as of November 12, 2022.

B. Interpretation

Congress enacted the SSBA after the Commission had implemented its Safety Standard for Infant Sleep Products (ISP Rule; 16 CFR part 1236). The ISP Rule became effective on June 23, 2022, and applies to products "marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age" that are not subject to another CPSC sleep standard.⁴ The ISP Rule requires that the seat back or sleep surface angle for these products be 10 degrees or less from horizontal when measured as specified in part 1236. 86

³ The Commission also received comments beyond the scope of this final rule. Those comments are summarized in the Staff Briefing Package and available at www.regulations.gov. Many of the commenters provided context for the SSBA, sharing data on the extent of Sudden Infant Death Syndrome (SIDS) in the U.S. over various time periods. The American Academy of Pediatrics (AAP), for example, provided data that shows SIDS deaths since 2000 in the U.S. have not declined, despite extensive outreach and education campaigns on safe sleep practices for babies. Several commenters referred to an AAP report on SIDS/SUID (Sudden Unexpected Infant Death) that estimated 3,500 infant deaths per year. March of Dimes noted that "Rates of preterm birth are increasing . . . [with] disparities in birth outcomes between women and infants of color and their White peers. An estimated 700 women [die] from complications related to pregnancy each year and more than 22,000 babies die before their first birthday each year."

⁴ The other sleep standards currently are 16 CFR part 1218 (bassinets and cradles); 16 CFR part 1219 (full-size cribs); 16 CFR part 1220 (non-full-size cribs); 16 CFR part 1221 (play yards); and 16 CFR part 1222 (bedside sleepers).

FR 33022, 33060–61 (June 23, 2021). The SSBA, by its terms, applies to "inclined sleepers for infants," defined as "a product with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old." 15 U.S.C. 2057d(b). Because the SSBA and the ISP Rule overlap but are not identical, the Commission sought comment on the following questions in particular:

1. How should the Commission interpret and implement the phrase "sleeping accommodations" for purposes of the SSBA ban?

Comment B.1: Several commenters (children's product design facility Iron Mountains, the Juvenile Products Manufacturers Association (JPMA), and consumer advocacy groups Kids in Danger (KID) and Consumer Federation of America (CFA)) stated that CPSC should use the ISP Rule's definition of "sleeping accommodations" to interpret the same language in the SSBA.

Commenters including KID, AAP, U.S. Public Interest Research Group (PIRG), Consumer Reports, CFA, March of Dimes, and Public Citizen, stated that "sleeping accommodations" should apply to products marketed for any kind of sleep, including napping or resting. KID stated that words such as "rest" or "nap," or statements such as "not for overnight, unattended or extended sleep," should not exclude a product from being considered a sleep product. PIRG suggested that while many infants can and do fall asleep anywhere, regardless of comfort, noise level or darkness, CPSC should define "sleeping accommodations" as products in which parents or caregivers believe an infant can sleep and stay unattended because of the way the product is designed, intended, or marketed. Consumer Reports stated that the term should apply broadly to include products remarketed as soothers or loungers.

The March of Dimes stated that CPSC should consider "sleeping accommodations" to be any product that is designed, intended, marketed, or commonly used by consumers for the purpose of putting a child to sleep, particularly if the sleep is unattended by an adult.

KID stated that the definition should include not just self-contained products, but also inclined sleep positioners, accessory products, and wedges that are used in the sleep environment.

Response B.1: The SSBA does not define "sleeping accommodations." In the preamble to the ISP Rule, the Commission explained that sleeping accommodations are "products that are

marketed or intended for both extended, unattended sleep, and also napping, snoozing, and other types of sleep in which a parent may or may not be present, awake, and attentive.” 86 FR 33047. The Commission agrees with commenters that “sleeping accommodations” should refer to products in which infants are placed for the purpose of napping or overnight sleep regardless of whether the sleep is “attended or supervised,” and that utilizing the same interpretation of sleeping accommodations in these overlapping rules will reduce confusion for the public and industry. Therefore, the Commission interprets the phrase “sleeping accommodations” in the SSBA consistent with the term as used in the ISP Rule. See 86 FR 33025–26.

2. What, if any, effect should inclusion of the term “designed” in the SSBA have on the Commission’s interpretation and implementation of the SSBA as compared to the ISP Rule?

Comment B.2: Comments from pediatricians and other medical professionals, as well as from AAP, stated that CPSC should be alert to changes to product marketing or categorization that could be cited as justification for the continued sale of dangerous products.

Multiple commenters, including KID, March of Dimes, CFA, Consumer Reports, and AAP, stated that by including the term “designed” in the statutory text, Congress sought to comprehensively ban all inclined sleep products and prohibit rebranding or reclassification of products to evade regulatory attention. These commenters stated that use of the word “designed” signals Congress’s intent to ban products that caregivers would reasonably see as suitable for sleep, regardless of how they are marketed.

One doctor (Hauck) advocated removing inclined products from the market, regardless of whether they are marketed for sleeping or awake infants, stating that “manufacturers will attempt to market these items for infants who are not shown to be sleeping . . . [but] infants placed in these products will fall asleep and then be at risk for dying in them.” The AAP stated although caregivers may believe inclined sleep products aid with gastroesophageal reflux, research shows that placing infants on their backs on inclined surfaces is ineffective in reducing gastroesophageal reflux and may result in the infant sliding into a position that could compromise breathing.

PIRG and Public Citizen asserted that the addition of the word “designed” will allow CPSC to review the design as

well as the marketing of inclined sleep products. These commenters stated that focusing on the manufacturer’s stated intent or consumer-facing marketing would enable manufacturers to argue that a product is not meant for sleep, when common sense dictates otherwise based on the design. These commenters urged the Commission to consider a product’s design, in addition to the company’s stated intention or marketing. Several commenters stated that if the product is not designed for any other purpose, then a logical conclusion is that the product is designed for sleep.

A children’s product design facility (Iron Mountains) stated that caregivers need products that restrain supervised, awake infants so that they can complete daily tasks and that swings, rockers, and bouncers are intended for such situations, and are the only alternative to the sofa or other unsafe surfaces. JPMA asserted that “infant rockers, swings, and bouncers are not designed to provide children with a place to sleep” and that any decision to include in the scope of the ban products that are not designed for sleep would misinterpret Congressional intent. JPMA further stated that if Congress had intended to include rockers, swings, and bouncers in the SSBA, it would have explicitly done so.

Response B.2: The Commission agrees that to give effect to the word “designed” within the definition of “inclined sleeper for infants” in the SSBA, the Commission should interpret that word as supplementing the accompanying words “intended” and “marketed.” In the ISP Rule, the Commission identified characteristics to be considered in evaluating whether a product is intended for sleep, including product packaging, marketing materials, instructions, product design, and pictures of consumer usage. See, e.g., 86 FR 33048, <https://www.cpsc.gov/Business-Manufacturing/Business-Education/Business-Guidance/Infant-Sleep-Products-Business-Guidance-and-Small-Entity-Compliance-Guide>. To assess product design, the Commission will consider a number of factors, including those set forth in Response B.3 below.

In the absence of otherwise conclusive evidence regarding design, previous marketing for sleep, while not dispositive, will be persuasive evidence that an inclined product was designed to provide sleeping accommodations. Similarly, if an inclined product’s design is materially the same as another product that is an inclined sleeper for infants, that would be persuasive, though not dispositive, evidence that

the product is designed to provide sleeping accommodations. Products that are designed to provide sleeping accommodations but also for one or more other purpose(s) likewise are covered by the language of the statutory ban, despite having the other, non-sleep use(s).

3. In the SSBA, what product characteristics, if any, demonstrate that a product is “designed” for sleep?

Comment B.3: Commenters from consumer safety advocacy groups, such as AAP, KID, PIRG, Consumer Reports, Public Citizen, and CFA, suggested product features they consider indicative of a product “designed” for sleep, including: padded sides; excess padding or pillow-like items; soothing sounds, lights, or vibrations; a nest-like appearance; muted color schemes, nighttime themes; illustrations of sleeping animals or closed eyes; warning labels that fail to warn against infant sleep generally and warn only against specific types of sleep, such as “prolonged,” “unattended,” or “overnight” sleep; and no features for another primary purpose, such as feeding or transportation of the child. The March of Dimes identified the following factors that it views as indicators a product is designed for sleep: a focus on comforting an infant to a point it could easily fall asleep in the product; nothing designed to stimulate an infant or prevent a child from sleeping; an absence of non-sleep related purposes, such as feeding or transportation; emphasis on the ability to leave a child unattended, where it may fall asleep.

Several commenters, including AAP, PIRG, Consumer Reports, and CFA, also stated that a product is designed for sleep if the purpose is to position an infant at an angle with the intent of leaving the infant in the product unattended during routine sleep, or if the product is intended to relax an infant in a way that it is reasonably expected the infant will fall asleep and be left unattended. PIRG gave examples of products with other primary purposes that involve supervised use, including high chairs, which are designed for feeding; car seats, which are designed for travel in a motor vehicle; and strollers, which are designed to contain a child being pushed on a walk.

JPMA stated that a “product designed for sleep would be constructed with features that are specifically intended to accommodate an unattended sleeping infant.” Iron Mountains stated that sleep products generally have “flat, horizontal occupant surfaces with no contour, shaping, or restraint” and are generally

larger than “awake time” products. Iron Mountains further stated that a product is designed, intended, and marketed for sleep if it is visually very similar to a play yard, bassinet, crib, or bedside sleeper, and features include some of or all of the following: vertical side-walls, high side-walls indicating containment, typically a distinct angle between the occupant surface and the side walls, generally large size, flat and horizontal sleep surface with little or no contouring, and lack of a restraint.

Response B.3: The Commission agrees with commenters’ identification of characteristics that could be relevant to distinguishing whether products are designed for infant sleep for purposes of the SSBA, including, but not limited to: padded sides; excess padding or pillow-like items; soothing sounds, motions, lights, or vibrations; nighttime themes; and labels that warn only against specific types of sleep and not sleep generally.

4. How should the Commission interpret and implement the terms “marketed” and “intended” as a sleeping accommodation in the SSBA? Should these terms be interpreted and implemented the same as in the ISP Rule? Why or why not?

Comment B.4: JPMA, AAP, PIRG, Consumer Reports, CFA, and KID stated that the terms “marketed” and “intended” should be interpreted and implemented under the SSBA consistent with how they are discussed in the preamble to the ISP Rule. AAP added that evaluation of marketing and intent should include assessment of marketing and promotional materials, audience targeting (including algorithms), the firm’s public and private communications about a product, and the firm’s foreseeable awareness about a product (including images, consumer comments, and discussion on social media and product review pages regarding the use of the product for routine sleep). KID added that while the terms “marketed” and “intended” overlap, together they “paint a line between infant products that have other purposes such as play, interaction, transport or feeding and those products [for which] . . . sleep is clearly an intended purpose.”

Response B.4: In the preamble of the ISP Rule, the Commission stated that “if a product’s packaging, marketing materials, inserts, or instructions indicate that the product is for sleep, or includes pictures of sleeping infants, then CPSC will consider the product to be marketed for sleep.” 86 FR 33063. The Commission also stated that staff will consider a “[m]anufacturer’s intent,

which can be evaluated through stated warning messages, marketing photos, product instructions and other factors.” *Id.* at 33051. Consistent with the comments received in response to the NPR for this final rule, and to promote ease of administration and clarity for regulated parties, the Commission adopts for administration of the SSBA and this final rule the same interpretation of “marketed” and “intended” as exists for the ISP Rule. Therefore, for example, if a manufacturer or importer markets a product as a space for infant sleep, the product will fall within the scope of the SSBA and this final rule and must meet the requirement to have a sleep surface angle of not greater than ten degrees.

5. What is the significance of the age distinction between the ISP Rule and the SSBA’s ban? How might this difference bear on implementation of the SSBA as compared to the ISP Rule, including with respect to developmental differences between a newborn to 5 month old as identified in the ISP Rule, versus a newborn to 1 year old as identified in the SSBA?

Comment B.5: JPMA stated that while most sleep products within the scope of the SSBA already fall within the scope of the ISP Rule because they are marketed for children 5 months or younger, the broader age range in the SSBA could prevent “bad actors” from re-marketing such products for infants 6 months to a year in an attempt to evade the ISP Rule.

AAP and Consumer Reports commented that important differences exist in the hazards for younger versus older infants, because there are significant developmental differences between infants who are newborn to 5 months old and those between 5 months and 1 year of age. AAP identified the following differences between older and younger infants:

- Older infants have greater arm strength and the ability to roll and change body positions, including from supine to prone;
- Older infants have increased head and neck muscle strength;
- Older infants generally have the ability to lift and hold up their heads;
- Older infants have more mature brain development, which enables regulation of autonomic nervous functions, including breathing;
- Older infants in the 9-to-12-month range tend to face more danger from strangulation from straps, restraints, and other loose hazards on sleep products; and

- Younger infants are at greater risk of positional asphyxia and the other biomechanical hazards.

Public Citizen recommended that the Commission address the differences in hazard patterns by age group and make sure products for children up to 1 year of age are included in the scope of the final rule. KID stated that the risk to infants over 5 months is important and noted they had recommended expanding the age range in response to the NPR for the ISP Rule. KID emphasized that the SSBA will prevent new inclined sleep products marketed for 6 months and older from entering the marketplace, deter remarketing of existing products, and provide CPSC with the authority to remove all inclined sleepers marketed for children up to 1 year from the marketplace.

CFA stated that the SSBA, by including infants up to 1 year, broadens CPSC’s authority to include inclined sleep products for infants over 5 months. CFA also noted that the expanded age range prevents suppliers from remarketing infant products to an older age group to evade the ISP Rule, when those products are not suitable for an older child.

Response B.5: As commenters note, AAP’s safe sleep guidance states that infants less than 1 year old should sleep on a firm, flat, surface, such as a crib, bassinet, play yard, or bedside sleeper.⁵ Consistent with that guidance, the SSBA and this final rule prohibit inclined sleeping accommodations with an incline of greater than 10 degrees for all children from birth up to 1 year of age.

6. How, if at all, should the SSBA’s ban of inclined sleepers for infants affect the ISP Rule or the Commission’s application of it?

Comment B.6: Commenters largely expressed support for the continued implementation and enforcement of the ISP Rule, without change. AAP and Consumer Reports stated that the SSBA should build upon the successful foundation of the ISP Rule to offer clarity on the importance of banning all inclined infant sleep products, such as by including more extensive examination of products to ensure that if a product is not intended for another purpose (such as travel or eating) and can be used for routine sleep, it does not have an incline greater than 10 degrees.

⁵ “Place infants on their backs for sleep in their own sleep space with no other people. Use a crib, bassinet, or portable play yard with a firm, flat mattress and a fitted sheet. Avoid sleep on a couch or armchair or in a seating device, like a swing or car safety seat (except while riding in the car).” www.aap.org/en/patient-care/safe-sleep/.

Response B.6: Although the ISP Rule and the SSBA differ somewhat, commenters did not identify any conflict between them. Therefore, the Commission finds no reason to propose changes to the ISP Rule.

7. To the extent inclined sleepers remain on the market that are not banned by this rule, and that are not regulated under the ISP Rule, should CPSC require testing and certification to this ban, to demonstrate that a product is not within the scope of the ban?

Comment B.7: Commenters differed as to whether testing and certification under the SSBA are needed and what such testing would achieve. JPMA opposed testing and certification to demonstrate that inclined sleep products are not banned products pursuant to the SSBA. JPMA further stated that a product with an incline of less than 10 degrees would not meet the definition of an “inclined sleeper for infants” in the SSBA.

Consumer groups supported SSBA testing and certification. AAP stated that CPSC should use its authority to require testing and certification to ensure that noncompliant products are not sold. KID and Consumer Reports supported testing and certification to demonstrate which products are out of scope of the ban and thus allowed for sale, stating that testing and certification could demonstrate that an inclined sleep product either for older children or with an incline under 10 degrees is not within the scope of the ban. Consumer Reports stated that testing and certification would help to eliminate potential loopholes and avoid muddling the longstanding “bare is best” messaging for safe infant sleep. CFA also supported testing, urging the CPSC to use all of its authority, including enforcement, testing, and certification, to protect infant sleep environments.

Response B.7: The NPR noted that when a ban does not remove all products in a product category from the market, CPSC may require testing and certification to demonstrate that a product is not within the scope of the ban. Few bans completely remove all products in a specific category from the market, instead removing a subset of products with hazardous characteristics, while allowing sale of other products in the category subject to regulation. The Commission has previously stated that manufacturers of products in a category where a subset of the products are subject to a ban must issue certificates. 28 FR 28079, 28082 (May 13, 2013). Moreover, section 14(a)(1) of the CPSA requires that products subject to a rule, ban, standard, or regulation, be tested

and certified as compliant. 15 U.S.C. 2063(a)(1).

Congress did not prohibit all inclined sleepers for infants in the SSBA—only those intended, marketed, or designed for infants from birth to 1 year that have an incline greater than ten degrees. Therefore, products may remain in the marketplace that could be subject to regulation. Though the Commission is not implementing a testing and certification program at this time, it may consider testing, certification, and registration requirements in the future, based on additional information collected by the agency.

IV. Changes Included in the Final Rule

The final rule contains three changes from the NPR: the effective date and two minor technical or clarifying revisions.

A. Effective Date

The APA generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). The NPR proposed an effective date of November 12, 2022, which was the date that the SSBA took effect. Because that date has passed, and because commenters supported CPSC implementing the rule expeditiously, the Commission is finalizing this rule with a 30-day effective date, the minimum permitted under the APA, and has revised 16 CFR 1310.4 accordingly. Section 1310.4 was further revised to clarify that the ban of inclined sleepers for infants was effective as of November 12, 2022, pursuant to the SSBA, but that the final rule is effective as of September 15, 2023. The promulgation of this final rule does not change the fact that inclined sleepers have been banned pursuant to the SSBA since November 12, 2022.

B. Technical and Clarifying Revisions

For the final rule, the Commission has updated the language proposed in the NPR by replacing the public law citation for the SSBA (Pub. L. 117–126) with the newer U.S. Code citation (15 U.S.C. 2057d).

The Commission also revised proposed 16 CFR 1310.1, *Purpose and scope*, to more fully describe the substantive effect of Congress’s classification of inclined sleepers for infants as banned hazardous products. Section 1310.1 of the final rule makes clear that the rule prohibits not only the sale of inclined sleepers for infants but also, in accordance with section 19(a)(1) of the CPSA, the offer for sale, manufacture for sale, distribution in commerce, or importation into the

United States, of these products. 15 U.S.C. 2068(a)(1).

V. Preemption

Section 3(b)(2)(A) of Executive Order 12988, *Civil Justice Reform* (Feb. 5, 1996), directs agencies to specify the preemptive effect of any rule. 61 FR 4729 (Feb. 7, 1996). Because the SSBA states that inclined sleepers for infants are banned hazardous products, any state performance standards allowing the sale of inclined sleepers for infants, as those products are defined in the SSBA and this rule, would be inconsistent with Federal law and therefore preempted by this ban.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601–612, requires that agencies review proposed and final rules for their potential economic impact on small entities, including small businesses, and identify alternatives that may reduce such impact, unless the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. In the NPR, the Commission certified that the rule will not have a significant economic impact on substantial number of small entities and received no comment on that issue. 87 FR 44309.

VII. Environmental Considerations

The Commission’s regulations at 16 CFR part 1021 address whether the agency must prepare an environmental assessment or an environmental impact statement. Under those regulations, certain categories of CPSC actions that have “little or no potential for affecting the human environment” do not require an environmental assessment or an environmental impact statement. 16 CFR 1021.5(c). This final rule codifying section 2 of the SSBA falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

VIII. Paperwork Reduction Act

This final rule contains no information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3521).

IX. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that, before a rule can take effect, the agency issuing the rule must submit the rule and certain related information to each House of Congress and the Comptroller

General, 5 U.S.C. 801(a)(1), and indicate whether the rule is a “major rule” as defined in 5 U.S.C. 804(2). The CRA further states that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a “major rule.” OIRA has determined that this rule is not a “major rule” under the CRA. To comply with the CRA, the Commission will submit the required information to each House of Congress and the Comptroller General.

List of Subjects in 16 CFR Part 1310

Administrative practice and procedure, Consumer protection, Infants and children.

■ For the reasons stated in the preamble, the Commission adds part 1310 to title 16 of the Code of Federal Regulations as follows:

PART 1310—BAN OF INCLINED SLEEPERS FOR INFANTS

- Sec.
- 1310.1 Purpose and Scope.
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Authority: 15 U.S.C. 2057d.

§ 1310.1 Purpose and Scope.

The purpose of this rule is to prohibit the sale, offer for sale, manufacture for sale, distribution in commerce, or importation into the United States, of any inclined sleepers for infants, as defined in part 1310.2 and as set forth in the Safe Sleep for Babies Act of 2021 (15. U.S.C. 2057d).

§ 1310.2 Definition.

Inclined sleeper for infants means a product with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old.

§ 1310.3 Banned Hazardous Product.

Any inclined sleeper for infants, as defined in section 1310.2, regardless of the date of manufacture, is a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057).

§ 1310.4 Effective Date.

By statute, the effective date of this ban is November 12, 2022. The effective date of this rule is September 15, 2023.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 500, 510, 516, 520, 522, 524, 526, 529, 556 and 558

[Docket No. FDA–2023–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications, Change of Sponsor, Change of Sponsor Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and conditionally approved new animal drug applications (cNADAs) during April, May, and June 2023. FDA is informing the public of the availability

of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve their accuracy and readability.

DATES: This rule is effective August 16, 2023.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs, ANADAs, and cNADAs during April, May, and June 2023, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: <https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room>. Marketing exclusivity and patent information may be accessed in FDA’s publication, Approved Animal Drug Products Online (Green Book) at: <https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book>.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs, ANADAs, AND CNADAs APPROVED DURING APRIL, MAY, AND JUNE 2023 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS

Approval date	File No.	Sponsor	Product name	Effect of the action	Public documents	21 CFR section
April 5, 2023	200–612	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	BIMASONE (flumethasone) Injectable Solution.	Original approval for the treatment of various inflammatory conditions in horses, dogs, and cats as a generic copy of NADA 030–414.	FOI Summary	522.960c
April 10, 2023	038–439	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666.	TERRAMYCIN for Fish (oxy- tetracycline) Type A Medicated Article.	Supplemental approval for the control of mortality due to columnaris disease in catfish and freshwater-reared salmonids.	FOI Summary	558.450