Rules and Regulations

Federal Register

Vol. 82, No. 52

Monday, March 20, 2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 801 and 1100

[Docket No. FDA–2015–N–2002]

RIN 0910–AH19

Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding ''Intended Uses''; Further Delayed Effective Date; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; further delay of effective date; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is further delaying the effective date of a final rule published in the **Federal Register** of January 9, 2017. In the **Federal Register** of February 7, 2017, we delayed until March 21, 2017, the effective date of the final rule. This action further delays the effective date of the rule until March 19, 2018. FDA has received a petition from affected parties which raises questions about the amendments to the regulations regarding ''intended uses'' and requests that FDA reconsider these amendments. FDA is further delaying the effective date to invite public comment on the important substantive issues raised by the petition and to allow additional time to fully evaluate these issues and any other issues raised in response to this request for comments. FDA is seeking input on some specific questions, and is also interested in any other pertinent information or comments stakeholders would like to provide regarding any aspect of the final rule, or with respect to issues relating to ''intended uses'' generally.

DATES: *Effective date:* The effective date for the rule amending 21 CFR chapter 1 published at 82 FR 2193 on January 9, 2017, delayed at 82 FR 9501 on February 7, 2017, is further delayed until March 19, 2018.

Comment date: Submit either electronic or written comments by May 19, 2017. For additional information on the comment date, see section III in **SUPPLEMENTARY INFORMATION.**

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–2002 for ''Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Uses'; Delayed Effective Date; Request for Comments.'' Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, 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: Robert Berlin, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4238, Silver Spring, MD 20993, 301–796–8828.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 25, 2015 (80 FR 57756), FDA issued a proposed rule entitled ''Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Uses.' '' This notice of proposed rulemaking proposed a new regulation (proposed 21 CFR 1100.5) to describe the circumstances in which a product made or derived from tobacco that is intended for human consumption will be subject to regulation as a drug, device, or a combination product under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The proposed rule also proposed certain changes to FDA's existing regulations describing the types of evidence that may be considered in determining a medical product's intended uses (see 21 CFR 201.128 (drugs) and 21 CFR 801.4 (devices)). These amendments were intended to clarify FDA's existing interpretation and application of these regulations (see 80 FR 57756 at 57761). Specifically, the amendments were intended to clarify that FDA would not regard a firm as intending an unapproved new use for an approved or cleared drug or device based solely on that firm's knowledge that its product was being prescribed or used by doctors for such use (see 80 FR 57756 at 57761). FDA proposed to delete the last sentence of the intended use regulations to provide this clarification, in addition to some other changes.

The proposed amendments to the existing intended use regulations were not intended to reflect a change in FDA's approach regarding evidence of intended use for drugs and devices: FDA's longstanding position is that, in determining a product's intended use, FDA may look to any relevant source of evidence (see 80 FR 57756 at 57757) (the product's labeling, promotional claims, and advertising, oral or written statements by a manufacturer or its representatives, circumstances surrounding the distribution or sale of a product, and other relevant evidence).

In the **Federal Register** of January 9, 2017, we published final regulations adding new 1100.5 to volume 21 of the CFR and amending the intended use regulations found at 201.128 and 801.4. The provisions in the final rule amending the intended use regulations were modified from the proposed rule because of comments we received that suggested to us that the proposed changes might not provide adequate clarity to manufacturers (see 82 FR 2193 at 2207). Some comments appeared to misunderstand the limited scope of what FDA intended by the proposal, interpreting the proposal as signifying that FDA intended to eliminate manufacturer knowledge altogether as a source of evidence of intended use (see 82 FR 2193 at 2206). In addition, some comments requested that FDA narrow the scope of evidence relevant to determining intended use in ways inconsistent with FDA's longstanding position—for example, by removing manufacturer knowledge entirely from the types of evidence that may be considered in determining a product's intended use or by limiting evidence of intended use to a manufacturer's promotional claims (see 82 FR 2193 at 2206–2208)—further indicating potential misunderstanding of, and a lack of clarity with respect to, the proposed rule.

In issuing the amendments to the intended use regulations in the final rule, FDA's goal remained the same as it had intended in the proposed rule: To clarify that FDA would not regard a firm as intending an unapproved new use for an approved or cleared drug or device based solely on that firm's knowledge that its product was being prescribed or used by healthcare providers for such use (see 82 FR 2193 at 2206–07). Because of the comments described above, FDA decided that its clarification goals would be better achieved by amending the last sentence of each intended use regulation, rather than by deleting the sentences, and we revised the regulations accordingly (see 82 FR 2193 at 2206). The revised language was intended to achieve the goal described in the proposed rule, by amending the last sentence so that it no longer suggests that a manufacturer's mere knowledge that its approved or cleared product was being prescribed or used for an unapproved use would, on its own, be sufficient to establish a new intended use (see 82 FR 2193 at 2206). The revised sentence was also intended to embody FDA's longstanding position, discussed in the preamble to the proposed rule, that intended use can be based on ''any relevant source of evidence,'' including a variety of direct and circumstantial evidence (see 82 FR 2193 at 2206). The text of the final rule used the phrase ''the totality of evidence'' to accomplish these goals (see 82 FR 2193 at 2206).[1]

The rule was published with an effective date of February 8, 2017. On February 7, 2017, in accordance with the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Freeze Pending Review,'' FDA delayed the effective date of the rule until March 21, 2017 (82 FR 9501).

II. Rationale and Good Cause for a Further Delay of the Effective Date of the Final Rule

FDA has decided to delay the effective date for the final rule from March 21, 2017, until March 19, 2018. To the extent that 5 U.S.C. 553 applies to the delay of effective date from March 21, 2017, until March 19, 2018, the action is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A).

Alternatively, FDA's implementation of this action without opportunity for public comment, effective immediately upon publication in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Good cause exists to delay the prior rule without comment because the delay will ensure that the public is given an opportunity to comment on the final language that FDA included in the underlying final rule. A petition raising concerns with the final language was submitted by various industry organizations on February 8, 2017 (''petition'' and ''petitioners'').[2] The petition requests that FDA reconsider the amendments to the ''intended use'' regulations and promulgate a new final rule that, with respect to the intended use regulations at §§ 201.128 and 801.4, reverts to the language of the September 25, 2015, proposed rule. The petition also requests that FDA indefinitely stay the rule.

Petitioners ask that the final rule be stayed indefinitely and reconsidered for

[1] In the final rule, FDA also stated that the amendments were not intended to change or override FDA's existing guidance and ongoing proceedings regarding manufacturer communications regarding unapproved uses of approved or cleared products (see 82 FR 2193 at 2209–2210).

[2] See February 8, 2017 petition submitted by Ropes & Gray and Sidley Austin LLP on behalf of the Medical Information Working Group, the Pharmaceutical Research and Manufacturers of America, and the Biotechnology Innovation Organization, available in Docket Nos. FDA–2011–P–0512, FDA–2013–P–1079, FDA–2015–N–2002, and FDA–2016–N–1149 at *https://www.regulations.gov*.

two independent reasons (petition at pg. 10). First, they argue that the final rule was promulgated in violation of the fair notice requirement under the Administrative Procedure Act (APA) (petition at pgs. 10–13). Second, they argue that the ''totality of the evidence'' language in the final rule is a new and unsupported legal standard (petition at pgs. 10, 13–21). More specifically, the petitioners contend that the revisions to the intended use regulations run contrary to ''the settled interpretation'' of intended use (petition at pg. 2). They describe that settled interpretation in various ways, including as limiting evidence of intended use to ''manufacturer's claims,'' ''any relevant source *of claims,*'' ''labels on the drug or the 'labeling','' and ''objective evidence in promoting, distributing, *and* selling the [medical product]'' (petition at pgs. 2, 16, 17, 19) (emphases in original). Petitioners also state that, under existing law, a ''manufacturer *must* make an explicit promotional claim before FDA may find a new intended use'' (petition at pg. 19) (emphasis in original), and there is an exception for relying on circumstantial evidence ''only when its probative value is sufficient to *negate* any explanation other than the intended use of the product as a drug or device'' (petition at pg. 15) (emphasis in original). The petitioners interpret the proposed rule as acknowledging ''key limits'' on the scope of intended use (petition at pg. 7), and argue that under the proposed rule, intended use would have turned solely on the manufacturer's promotional statements (petition at pg. 11). The petitioners contend that the final rule unexpectedly expanded the understanding of intended use, and that adding the new final sentence referencing the ''totality of the evidence'' was a reversal of the proposed rule that violates the APA's notice-and-comment provisions (petition at pg. 11). Petitioners express the view that the wording used in the proposed rule would have helped to address substantial concerns they have regarding FDA's intended use definitions, while the final rule exacerbates those concerns (petition at pg. 11). These concerns include constitutional concerns (petition at pg. 19–21), and public health concerns related to chilling valuable scientific speech (petition at pg. 21).

These issues raised by the petition and similar concerns provide good cause to extend to the effective date of the rule without comment on the extension, so as to receive full public comments on these underlying issues and afford us enough time to collect and consider those comments.[3] Moreover, to the extent that petitioners (and/or others) misunderstood FDA's intent in proposing the revisions to the intended use provisions, the new comment period should provide additional opportunity to comment on FDA's approach, including a fair opportunity to comment on the language chosen in the final rule. This action should not be construed to suggest that FDA has made any decisions about the substantive arguments made in the petition.

Seeking public comment on this delay of the effective date is impracticable, unnecessary, and contrary to the public interest. The delay in the effective date until March 19, 2018, is necessary to give the public a fair opportunity to fully comment, and FDA the opportunity to further evaluate and consider the issues raised by the petition in addition to any other pertinent information or comments stakeholders submit to this docket regarding the final rule. Given the imminence of the effective date, seeking prior public comment on this delay would have been impracticable, as well as contrary to the public interest in the orderly issuance and implementation of regulations. However, in accordance with 21 CFR 10.40(e)(1), FDA will also accept comments for a period of 60 days on whether this rule delaying the effective date should be modified or revoked.

This action is being taken under FDA's authority under 21 CFR 10.35(a). The Commissioner of Food and Drugs finds that this delay of the effective date is in the public interest.

III. Issues for Comment and Consideration

In addition to other comments, FDA is soliciting comments from interested persons in particular on the issues raised in the petition. For ease of reference, these comments should be submitted to this existing public docket, FDA–2015–N–2002. We request that any additional data and information be submitted to FDA by May 19, 2017 to allow us to fully consider it. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 19, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of May 19, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

We are interested in comments on the petitioners' views on the proper interpretation of ''intended use.'' FDA solicits comment on the appropriateness of the various limitations suggested by petitioners, including limiting the evidence that may be considered to establish a product's intended use to the manufacturer's or distributor's promotional statements; requiring that a manufacturer make an explicit promotional claim before FDA may find a new intended use; and allowing an exception for relying on circumstantial evidence ''only when its probative value is sufficient to *negate* any explanation other than the intended use of the product as a drug or device'' (petition at pgs. 11, 19, 15) (emphasis in original). We are also interested in comments on the public health implications of limiting evidence of intended use as suggested by the petitioners, including with respect to the exchange of valuable scientific speech, or otherwise.

As explained in the preambles to the proposed and final rules: In determining intended use, the consideration of evidence such as the circumstances surrounding the distribution of a product, the known effects of a product or substance, and/or the context in which the product is sold often ensures that firms that attempt to evade FDA's medical product regulation by making no claims, or at least no explicit claims, about their products can be held accountable (see 80 FR 57756 at 57757; 82 FR 2193 at 2196). A few examples of situations in which evidence of intended use has been derived from sources other than explicit promotional claims are:

- Persons distributing substances which are known to be used recreationally to get high, such as Dextromethorphan (the active ingredient in some cough suppressants) and Nitrous Oxide (which is a prescription drug). See, *e.g., United States* v. *Johnson,* 471 F.3d 764, 765 (7th Cir. 2006); *United States* v. *Schraud,* 2007 U.S. Dist. LEXIS 89231, 3–6 (E.D. Mo. Dec. 4, 2007); *United States* v. *Travia,* 180 F. Supp. 2d 115, 119 (D.D.C. 2001); *United States* v. *LA Rush,* 2:13-cr-00249, First Superseding Information (C.D. Cal. April 3, 2014).
- Persons distributing synthetic drugs, such as synthetic marijuana, labeled as incense, potpourri, or bath

[3] We also note that a related issue, manufacturers' communications about unapproved uses of approved/cleared medical products, is currently the subject of a public docket with an open comment period; extending the effective date and taking comment on the issues raised with respect to this final rule provides FDA with the opportunity for contemporaneous consideration and resolution of these related issues.

salts, and/or bearing the statement ''not for human consumption.'' See, *e.g., United States* v. *Carlson,* 810 F.3d 544 (8th Cir. 2016), *cert. denied,* 137 S. Ct. 102, 291, 292 (2016); *United States* v. *Carlson,* 12-cr-00305–DSD–LIB, Amended Superseding Indictment (D. Minn. Sept. 11, 2013) and Court's Instructions to the Jury, (D. Minn. Oct. 8, 2013); *United States* v. *Bowen,* 14-cr-00169–PAB, Indictment (D. Colo. May 5, 2014) and Rule 11(c)(1)(A) and (B) Plea Agreement and Statement of Facts Relevant to Sentencing (D. Colo. Jan. 29, 2015).

- Persons distributing imitation drugs claimed to be incense or dietary supplements, such as imitation cocaine or imitation Ecstasy. See, *e.g., United States* v. *Storage Spaces Designated Nos.* ''*8*'' *&* ''*49*'', 777 F.2d 1363, 1366 (9th Cir. 1985); *United States* v. *Undetermined Quantities of . . . Street Drug Alternatives,* 145 F. Supp. 2d 692 (D. Md. 2001).
- Persons distributing products containing the active ingredients in prescription drugs, such as VIAGRA, CIALIS, LEVITRA, or BOTOX, as less expensive alternatives to the approved products, with labeling that states that they are ''all natural'' or ''herbal'' supplements or ''for research only.'' See, *e.g., United States* v. *Dessart,* 823 F.3d 395 (7th Cir. 2016); *United States* v. *Zeyid,* 1:14-cr-0197, First Superseding Indictment (N.D. Ga. June 24, 2014) (see also *https://www.justice.gov/usao-ndga/pr/atlanta-man-convicted-illegally-importing-and-distributing-male-enhancement-products*); *United States* v. *Livdahl,* 459 F. Supp. 2d 1255, 1260 (S.D. Fla. 2005).
- Other instances where a person's claims about the intended use of a product are belied by the person's activities or non-promotional statements or by circumstantial evidence. See, *e.g., United States* v. *An Article of Device Toftness Radiation Detector,* 731 F.2d 1253, 1257 (7th Cir. 1984); *United States* v. *789 Cases of Latex Surgeons' Gloves,* 799 F. Supp. 1275, 1294–1295 (D.P.R. 1992).

In these situations, the evidence relied on has included general knowledge of actual use by customers to get high or to achieve some other mind-altering effect; the known effects of a product or substance; implied claims from using names that sound similar to the names of controlled substances; the circumstances surrounding the sale (*e.g.,* a rock concert venue; receiving the product in bulk and repackaging into smaller plastic bags; the use of private email addresses; the absence of labeling); shipping orders, other correspondence, and memoranda relating to marketing and distribution; statements made in training sessions; and admissions.

Evidence other than promotional claims has also been used to establish that products offered for import into the United States without labeling or other claims that identify them as a drug or device are in fact intended for use as a drug or device, and are therefore subject to refusal if they fail to meet certain requirements for importing medical products (see 21 U.S.C. 381(a)(3)). For example, the defendants in *United States* v. *Zeyid,* 1:14-cr-0197, First Superseding Indictment (N.D. Ga. June 24, 2014) (see also *https://www.justice.gov/usao-ndga/pr/atlanta-man-convicted-illegally-importing-and-distributing-male-enhancement-products*), imported products containing active ingredients that were the same as those used in prescription drugs but that were labeled as ''tea,'' ''coffee,'' and ''beauty products.'' Another example of a setting where FDA commonly relies on non-promotional information in determining intended use is when evaluating whether research studies involving human subjects must be conducted under an investigational new drug application or investigational device exemption (see 21 CFR parts 312 and 812). For example, FDA commonly evaluates materials such as research protocols in determining whether studies of products that are marketed as dietary supplements, conventional foods, or cosmetics are evaluating such products for use as drugs and are therefore subject to the investigational new drug application requirements under part 312. Non-promotional information regarding the purpose of the research is relevant to establishing whether the product should be considered a drug for the purpose of the investigation.

With respect to the petitioners' suggested approaches to: (1) Limit the evidence relevant to determining the intended use of a medical product to promotional claims; (2) require that a manufacturer make an explicit promotional claim before FDA may find a new intended use; and/or (3) allow an exception for relying on circumstantial evidence ''only when its probative value is sufficient to *negate* any explanation other than the intended use of the product as a drug or device,'' and in light of the background described above regarding situations in which evidence of intended use has been derived from sources other than explicit promotional claims, we are particularly interested in comments on the following questions:

1. How should FDA consider situations such as those outlined above where companies and individuals distribute medical products and/or seek to import medical products without explicit promotional claims as we evaluate whether to adopt any of petitioners' suggested approaches to determining intended use?

2. What are the potential public health consequences, positive and negative, that should be considered in evaluating whether to adopt any of petitioners' suggested approaches to determining intended use? What other policy considerations are relevant when assessing approaches to intended use?

3. To the extent that your comment cites to First Amendment considerations as the legal rationale underlying your recommendations, how (if at all) do those considerations apply to the use of non-speech evidence in determining intended use, such as the circumstances surrounding the distribution of a product or the context in which it is sold?

4. In light of the petitioners' concerns about the language in the final rule, do stakeholders believe there is a distinction between considering ''any relevant source of evidence'' and ''the totality of evidence''? Do stakeholders have suggestions about what wording provides the most clarity to regulated entities?

These questions are not meant to be exhaustive; we are also interested in any other pertinent comments or information stakeholders would like to share regarding the final rule, including whether there are other approaches to ''intended use'' that FDA should consider. Please note that, as mentioned in the final rule (see 82 FR 2193 at 2209), FDA is currently engaged in a comprehensive review of its regulations and policies governing firms' communications about unapproved uses of approved/cleared medical products, and has established a separate public docket to receive written comments on that topic (see 81 FR 60299, September 1, 2016, available at: *http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm489499.htm*). As part of that separate proceeding, FDA is seeking input on a number of questions (see 81 FR 60299 at 60302–60303). To the extent the commenters wish to provide feedback on those questions rather than on the issues addressed here, that feedback should be submitted to that separate docket, which is open until April 19, 2017; however, we encourage commenters to submit to this docket their feedback on issues addressed in the separate docket to the extent that the feedback may also be pertinent to the final rule (including the preamble),

''intended use,'' and/or the specific issues raised herein.

IV. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, 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 as defined by Executive Order 12866 and Executive Order 13771.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the clarifications in this final rule will not significantly increase costs on manufacturers of products made or derived from tobacco, we certify 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 will not result in an expenditure in any year that meets or exceeds this amount.

We will delay the effective date of the final rule by 1 year. As shown in table 1, this action will generate a cost savings of $112,865 in one-time costs with a 7 percent discount rate and a cost savings of $50,249 in one-time costs with a 3 percent discount rate. Annualized over 10 years, a 1-year delay will save $16,069 with a 7 percent discount rate and $5,891 with a 3 percent discount rate. We expect that the final rule will reduce regulatory ambiguity and uncertainty, and, thus, reduce the regulatory and compliance burdens associated with such ambiguity. Although we did not quantify these benefits, we anticipate that delaying the effective date will reduce the benefits by a similar magnitude as the cost savings. For any final rule issued during or after the 1-year delay, we will analyze the impacts of such a rule.

TABLE 1—TOTAL ONE-TIME COST SAVINGS FROM A 1-YEAR DELAY OF THE EFFECTIVE DATE OF THE FINAL RULE

	Total one-time costs at 7 percent	Annualized one-time costs over 10 years at 7 percent	Total one-time costs at 3 percent	Annualized one-time costs over 10 years at 3 percent
Costs with Compliance Date Unchanged	$1,725,225	$245,633	$1,725,225	$202,249
Costs with Compliance Date Delayed 1-Year	1,612,360	229,564	1,674,976	196,358
Cost Savings	(112,865)	(16,069)	(50,249)	(5,891)

Table 2 shows the revised estimate of costs and benefits with a 1-year delay of the effective date.

TABLE 2—ECONOMIC DATA WITH 1-YEAR EFFECTIVE DATE DELAY: COSTS AND BENEFITS STATEMENT

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits							
Annualized Monetized $millions/year					7		
					3		
Annualized Quantified					7		
					3		
Qualitative	Reduce regulatory ambiguity						
Costs							
Annualized Monetized $millions/year	$0.230	$0.118	$0.341	2014	7	10 years	
	0.196	0.101	0.292	2014	3	10 years	
Annualized Quantified					7		
					3		
Qualitative							

TABLE 2—ECONOMIC DATA WITH 1-YEAR EFFECTIVE DATE DELAY: COSTS AND BENEFITS STATEMENT—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Transfers							
Federal Annualized Monetized $millions/year					7		
					3		
From/To	From:			To:			
Other Annualized Monetized $millions/year					7		
					3		
From/To	From:			To:			
Effects State, Local or Tribal Government: No Effect Small Business: No effect Wages: No estimated effect Growth: No estimated effect							

The full analysis of economic impacts is available in the docket for this final rule (FDA–2015–N–2002) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

V. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. *United States* v. *LA Rush,* 2:13–cr–00249, First Superseding Information (C.D. Cal. April 3, 2014).

2. *United States* v. *Carlson,* 12–cr–00305–DSD–LIB, Amended Superseding Indictment (D. Minn. Sept. 11, 2013).

3. *United States* v. *Carlson,* 12–cr–00305–DSD–LIB, Court's Instructions to the Jury, (D. Minn. Oct. 8, 2013).

4. *United States* v. *Bowen,* 14–cr–00169–PAB, Indictment (D. Colo. May 5, 2014).

5. *United States* v. *Bowen,* 14–cr–00169–PAB, Rule 11(c)(1)(A) and (B) Plea Agreement and Statement of Facts Relevant to Sentencing (D. Colo. Jan. 29, 2015).

6. *United States* v. *Zeyid,* 1:14–cr–0197, First Superseding Indictment (N.D. Ga. June 24, 2014).

7. U.S. Department of Justice, ''Atlanta Man Convicted of Illegally Importing and Distributing Male Enhancement Products from China'', Feb. 16, 2017, available at *https://www.justice.gov/usao-ndga/pr/atlanta-man-convicted-illegally-importing-and-distributing-male-enhancement-products.*

Dated: March 16, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–05526 Filed 3–17–17; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 22, 51, 124, 171, 300, and 770

[FRL–9960–28–OP]

Further Delay of Effective Dates for Five Final Regulations Published by the Environmental Protection Agency Between December 12, 2016 and January 17, 2017

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; further delay of effective dates.

SUMMARY: In accordance with the Presidential directive as expressed in the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Freeze Pending Review,'' and the **Federal Register** document published by EPA on January 26, 2017, EPA is further delaying the effective dates for the five regulations listed in the table below.

DATES: This regulation is effective March 21, 2017. The effective date of each regulation listed in the table below is delayed to a new effective date of May 22, 2017.

FOR FURTHER INFORMATION CONTACT: Sarah Rees, Director, Office of Regulatory Policy and Management, Office of Policy, Mail code 1804, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave NW., Washington, DC 20460; (202) 564–1986; *rees.sarah@epa.gov.*

SUPPLEMENTARY INFORMATION: On January 26, 2017, EPA published a document in the **Federal Register** entitled ''Delay of Effective Date for 30 Final Regulations Published by the Environmental Protection Agency Between October 28, 2016 and January 17, 2017'' (82 FR 8499) (January 26 Document). In that document, EPA delayed the effective dates of the five regulations listed in the table below to March 21, 2017, as requested in the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Freeze Pending Review'' (January 20 Memo). That memo directed the heads of Executive Departments and Agencies to temporarily postpone for 60 days from the date of the January 20 Memo the effective dates of all regulations that had been published in the **Federal Register** but had not yet taken effect.

The January 20 Memo also directs that where appropriate and as permitted by applicable law, agencies should consider a rule to delay the effective date for regulations beyond that 60-day period. In this document, EPA is taking action to further delay the effective dates for five regulations listed in the table below until May 22, 2017. EPA is taking this action to give recently arrived Agency officials the opportunity to learn more about these regulations and to decide whether they would like to conduct a substantive review of any of those regulations. If Agency officials decide to conduct a substantive review