DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 169

[Docket No. FDA–2020–N–1807]

RIN 0910–AI16

French Dressing; Revocation of a Standard of Identity

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is revoking the standard of identity for French dressing. This action, in part, responds to a citizen petition submitted by the Association for Dressings and Sauces (ADS). We conclude that this standard no longer promotes honesty and fair dealing in the interest of consumers. Revocation of the standard of identity for French dressing will provide greater flexibility in the product's manufacture, consistent with comparable, nonstandardized foods available in the marketplace.

DATES: This final rule is effective on February 14, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Rumana Yasmeen, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371, or Carrol Bascus, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary
A. Purpose of the Final Rule
B. Summary of the Major Provisions of the Final Rule
C. Legal Authority
D. Costs and Benefits
II. Background
A. Need for the Regulation/History of This Rulemaking
B. Summary of Comments to the Proposed Rule
III. Legal Authority
IV. Comments on the Proposed Rule and FDA Response
A. Introduction
B. Description of the Comments and FDA Response
V. Effective Date
VI. Economic Analysis of Impacts
VII. Analysis of Environmental Impact
VIII. Paperwork Reduction Act of 1995
IX. Federalism
X. Consultation and Coordination With Indian Tribal Governments
XI. References

I. Executive Summary

A. Purpose of the Final Rule

The final rule revokes the standard of identity for French dressing. This action, in part, responds to a citizen petition submitted by the ADS. We conclude that the standard of identity for French dressing no longer promotes honesty and fair dealing in the interest of consumers and revoking the standard could provide greater flexibility in the product's manufacture, consistent with comparable, nonstandardized foods available in the marketplace.

B. Summary of the Major Provision of the Final Rule

The final rule revokes the standard of identity for French dressing.

C. Legal Authority

We are issuing the final rule to revoke the standard of identity for French dressing consistent with our authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act), which directs the Secretary of Health and Human Services (Secretary) to issue regulations fixing and establishing for any food a reasonable definition and standard of identity, quality, or fill of container whenever, in the Secretary's judgment, such action will promote honesty and fair dealing in the interest of consumers.

D. Costs and Benefits

The final rule affects manufacturers of dressings for salad and does not require any of the affected firms within the industry to change their manufacturing practices.

Our analysis of current food manufacturing practices and the petition to revoke the standard indicate that revoking the standard of identity could provide benefits in terms of additional flexibility and the opportunity for innovation to manufacturers. The potential for innovation is evidenced by the growing variety of dressings for salads on the market that are formulated to meet consumers' preferences and needs.

Therefore, we conclude that the final rule to revoke the standard of identity for French dressing would provide social benefits at no cost to the respective industries.

II. Background

A. Need for the Regulation/History of This Rulemaking

Section 401 of the FD&C Act (21 U.S.C. 341) directs the Secretary to issue regulations fixing and establishing for any food a reasonable definition and standard of identity, quality, or fill of container whenever, in the Secretary's judgment, such action will promote honesty and fair dealing in the interest of consumers. The purpose of these standards is to protect consumers against economic adulteration and reflect consumers' expectations about food.

In the **Federal Register** of August 12, 1950 (15 FR 5227), we established a standard of identity for French dressing. We later amended that standard of identity in the **Federal Registers** of May 10, 1961 (26 FR 4012), February 12, 1964 (29 FR 2382), February 1, 1967 (32 FR 1127 at 1128), May 18, 1971 (36 FR 9010), and November 8, 1974 (39 FR 39554), to allow the use of certain ingredients in French dressing. We also re-designated the French dressing standard of identity as § 169.115 (21 CFR 169.115) (42 FR 14481, March 15, 1977).

We received a citizen petition from the ADS asking us, in part, to revoke the standard of identity for French dressing (citizen petition from the ADS, dated January 13, 1998, submitted to the Division of Dockets Management, Food and Drug Administration, Docket No. FDA–1998–P–0669 (''petition'')). As a partial response to the petitioner's request, we issued a proposed rule in the **Federal Register** of December 21, 2020 (85 FR 82980), that would revoke the standard of identity for French dressing.

The petition asked us to revoke the standard of identity for French dressing (petition at page 1). The petition stated that there has been a proliferation of nonstandardized pourable dressings for salads with respect to flavors (Italian, Ranch, cheese, fruit, peppercorn, varied vinegars, and other flavoring concepts) and composition (including a wide range of reduced fat, ''light,'' and fat-free dressings) (petition at page 3). The French dressing standard of identity, according to the petition, no longer serves as a benchmark for other dressings because of the wide variation in composition to meet consumer interests (id.). Instead, the petition claimed that the standard of identity has become marginalized and restricts innovation (id.). Therefore, the petition

stated that the French dressing standard of identity no longer promotes honesty and fair dealing in the interest of consumers (id.).

We reviewed the petition and tentatively concluded that the standard of identity for French dressing no longer promotes honesty and fair dealing in the interest of consumers. Therefore, we proposed to revoke the French dressing standard of identity at § 169.115.

When the standard of identity was established in 1950, French dressing was one of three types of dressings we identified (15 FR 5227). We generally characterized the dressings as containing a fat ingredient, an acidifying ingredient, and seasoning ingredients.

The French dressing standard allowed for certain flexibility in manufacturers' choice of oil, acidifying ingredients, and seasoning ingredients. Tomatoes or tomato-derived ingredients were among the seasoning ingredients permitted, but not required. Amendments to the standard since 1950 have permitted the use of additional ingredients, such as any safe and suitable color additives that impart the color traditionally expected (39 FR 39543 at 39554–39555).

Most, if not all, products currently sold under the name ''French dressing'' contain tomatoes or tomato-derived ingredients and have a characteristic red or reddish-orange color. They also tend to have a sweet taste. Consumers appear to expect these characteristics when purchasing products represented as French dressing. Thus, it appears that, since the establishment of the standard of identity, French dressing has become a narrower category of products than prescribed by the standard. These products maintain the above characteristics without a standard of identity specifically requiring them.

Additionally, French dressing products are manufactured and sold in lower-fat varieties that contain less than the minimum amount of vegetable oil (35 percent by weight) required by § 169.115(a). In the preamble to the proposed rule, we stated that we were unaware of any evidence that consumers are deceived or misled by the reduction in vegetable oil when these varieties are sold under names including terms such as ''fat free'' or ''low-fat'' (85 FR 82980 at 82982). By contrast, these varieties appear to accommodate consumer preferences and dietary restrictions.

Therefore, after considering the petition and related information, through the proposed rule, we tentatively concluded that the standard of identity for French dressing no longer promotes honesty and fair dealing in the interest of consumers consistent with section 401 of the FD&C Act and proposed to revoke the standard of identity for French dressing. The preamble to the proposed rule also noted that the proposed revocation is consistent with section 6 of Executive Order 13563, ''Improving Regulation and Regulatory Review'' (January 18, 2011), which requires agencies to periodically conduct retrospective analyses of existing regulations to identify those ''that might be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them'' accordingly.

B. Summary of Comments to the Proposed Rule

There were more than 20 comments to the proposed rule. A trade association, a business association, and individuals submitted the comments. Some comments appeared to have been submitted as part of a university course assignment. In general, most comments supported the revocation of the French dressing standard of identity; their reasons supporting the revocation ranged from promoting innovation, believing that consumers are not misled, or stating that the standard of identity was obsolete. A small number of comments misinterpreted the proposed rule as removing or prohibiting the use of the name ''French dressing,'' and one comment opposed revoking the standard of identity because of public health concerns.

III. Legal Authority

We are issuing this final rule to revoke the standard of identity for French dressing consistent with our authority under the FD&C Act, which directs the Secretary to issue regulations fixing and establishing for any food a reasonable definition and standard of identity, quantity, or fill of container, whenever, in the Secretary's judgment, such action will promote honesty and fair dealing in the interest of consumers.

IV. Comments on the Proposed Rule and FDA Response

A. Introduction

As stated earlier, there were more than 20 comments to the proposed rule. A trade association, a business association, and individuals submitted the comments. Several comments appeared to have been submitted as part of a university course assignment. In general, most comments supported the revocation of the French dressing standard of identity.

A small number of comments misinterpreted the proposed rule as removing or prohibiting the use of the name ''French dressing,'' and one comment opposed revoking the standard of identity because of public health concerns.

We describe and respond to the comments in section IV.B. of this document. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Description of the Comments and FDA Response

(Comment 1) Most comments supported revoking the standard of identity for French dressing. In general, the comments agreed with us that revoking the standard of identity would:

- Allow manufacturers to innovate their products in ways that consumers want;
- Give French dressing manufacturers the same treatment or flexibility to innovate or modernize their products as other dressing manufacturers have. One comment added that revoking the standard of identity for French dressing would enable manufacturers to substitute ingredients to address allergies, ingredient sensitivities, or even consumer preferences (particularly consumers on a diet); and
- Eliminate an obsolete standard that has not changed significantly over 70 years. Some comments added that consumers recognize French dressing and can judge for themselves whether to buy a particular product.

Other comments said that the standard of identity for French dressing is no longer needed to promote honesty and fair dealing for consumers. Some comments explained that State consumer protection laws and tort laws could protect consumer interests, while others said that consumers are able to determine a product's ingredients through ingredient labeling. One comment said that the standard of identity for French dressing was ''unnecessary red tape.''

(Response 1) We agree with the comments. The final rule revokes the standard of identity for French dressing.

(Comment 2) Some comments interpreted the proposed rule as eliminating the name ''French dressing.'' One comment said that

products marketed as French dressing range in color from orange to red and differ in taste, so the product should lose the ''title'' of French dressing. Another comment said that they did not understand why the name ''French dressing'' has to be ''revoked'' and that the consumer base for the dressing will be ''hurt'' if they look for products named French dressing and are unable to find them.

(Response 2) The comments may have misunderstood the scope of the proposed rule and the distinction between standards of identity and food names. Standards of identity are requirements related to the content and production of certain food products. They typically set forth permitted ingredients, both mandatory and optional, and sometimes describe the amount or proportion of each ingredient. They are established under the common or usual name of the food; however, a standard of identity does not need to be established for a food to be labeled with and sold under its common or usual name. Most foods are nonstandardized foods and are labeled with and sold under common or usual names that have been established by common usage. See 21 U.S.C. 343(i)(1) and 21 CFR 102.5(d). Revocation of the French dressing standard of identity will eliminate requirements related to the content and production of French dressing and effectively place French dressing in the category of nonstandardized foods. As a nonstandardized food, French dressing must be labeled with its common or usual name, ''French dressing,'' which is still in common usage. Thus, food products with the name French dressing will continue to be available to consumers.

(Comment 3) One comment objected to the proposed rule. The comment said that consumer health would be at risk because consumers would be unaware of changes before they buy the product and that manufacturers might use more ''fillers'' in a product so that it is less expensive to make. The comment said we should ''reconsider'' revoking the standard of identity for French dressing because ''it would ultimately put the health of consumers at a slight risk.''

(Response 3) As explained in the proposed rule, the standard of identity does not appear to constrain French dressing products currently on the market. French dressing has become a narrower category of products than prescribed by the standard. These products maintain their characteristics without a standard of identity specifically requiring them. In the absence of a standard of identity, manufacturers will have the flexibility to use different ingredients to produce products that meet consumer expectations for French dressing.

We received no information to support the assertion that manufacturers might use ''fillers'' to ''make the product cheaper to produce.'' It is unclear from the comment what ''fillers'' means, which ingredients this term would encompass, whether such ingredients are used in the manufacture of French dressing, whether such ingredients are prohibited under the standard of identity, and why the use of such ingredients in French dressing would constitute economic adulteration. We note that manufacturers must comply with the ingredient labeling requirements in 21 CFR 101.4. Therefore, consumers will still be informed about the ingredients in the French dressing they purchase.

We also disagree that revoking the standard of identity ''would ultimately put the health of consumers at a slight risk.'' The comment did not provide information discussing what the health risks would be, and we are unaware of any evidence that supports this statement.

(Comment 4) One comment said that it could not believe that the proposed rule was a priority.

(Response 4) We have the authority to issue regulations establishing standards of identity if it promotes honesty and fair dealing in the interest of consumers. Standards of identity are intended to protect consumers against economic adulteration, maintain the integrity of food, and reflect consumers' expectations about the food. This rulemaking is part of our comprehensive effort to modernize food standards to reduce regulatory burden and remove barriers to innovation. As stated in the proposed rule, it appears that French dressing has become a narrower category of products than prescribed by the standard (*e.g.,* most, or all contain tomatoes or tomato-derived ingredients, which the standard of identity does not require). These products maintain their characteristics without a standard of identity specifically requiring them. We conclude that a standard of identity for French dressing no longer promotes honesty and fair dealing in the interest of consumers. Therefore, we are revoking the standard of identity for French dressing.

This action is also consistent with our responsibilities under section 6 of Executive Order 13563, ''Improving Regulation and Regulatory Review'' (January 18, 2011), which requires agencies to periodically conduct retrospective analyses of existing regulations to identify those ''that might be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them'' accordingly.

V. Effective Date

This rule is effective on February 14, 2022.

VI. 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 believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we have concluded, as set forth below, that this rule would not generate significant compliance costs, 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 private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) 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.

The final rule affects manufacturers of salad dressings. Our review of supermarket scanner data for the year 2018 shows that a total of 227 distinct pourable products sold as ''French dressing'' that year were manufactured by 53 firms. The final rule does not require any of the affected firms to change their manufacturing practices. Our analysis of current food manufacturing practices and the petition to revoke the standard indicate

that revoking the standard of identity could provide benefits in terms of additional flexibility to the manufacturers of French dressing products. Revoking the standard of identity could provide an opportunity for innovation and the introduction of new French dressing products, providing benefits to both consumers and industry. Therefore, we conclude that the final rule, would provide social benefits at little to no cost to the respective industries (table 1).

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF FINAL RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized $millions/year	$0	$0	$0	2018	7		
					3		
Annualized Quantified					7		
					3		
Qualitative	Benefits to manufacturers would be from additional flexibility, and the opportunity for innovation regarding, French dressing products.						
Costs:							
Annualized Monetized $millions/year	0	0	0	2018	7		
					3		
Annualized Quantified					7		
					3		
Qualitative.							
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:							
Small Business:							
Wages:							
Growth:							

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(a) 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.

VIII. Paperwork Reduction Act of 1995

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

IX. 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.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XI. References

The following reference is on display at the Dockets Management Staff (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 website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. French Dressing: Revocation of a Standard of Identity: Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Unfunded Mandates Reform Act

Analysis available at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

List of Subjects in 21 CFR Part 169

Food grades and standards, Oils and fats, Spices and flavorings.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 169 is amended as follows:

PART 169—FOOD DRESSINGS AND FLAVORINGS

■ 1. The authority citation for part 169 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

§ 169.115 [Removed]

■ 2. Remove § 169.115.

Dated: January 6, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2022–00494 Filed 1–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. FDA–2019–N–3101]

RIN 0910–AI10

Revised Procedures for the Announcement of Approvals and Denials of Premarket Approval Applications and Humanitarian Device Exemption Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend the medical device regulations regarding the procedures for the announcement of approvals and denials of premarket approval applications (PMAs) and humanitarian device exemption applications (HDEs). This final rule discontinues the publication in the **Federal Register** after each quarter of a list of PMA and HDE approvals and denials announced in that quarter. We will continue to post approval and denial notices for PMAs and HDEs on FDA's home page on the internet and will also continue to make available on the internet and place on public display summaries of safety and effectiveness data (SSED) for PMAs and summaries of safety and probable benefit (SSPB) for HDEs. FDA is taking this action to improve the efficiency of announcing approvals and denials of PMAs and HDEs and to eliminate duplication in the current process for announcing this information. We are also updating Agency contact information and statutory references in certain sections of the PMA and HDE regulations for purposes of accuracy, clarity, and consistency.

DATES: This rule is effective February 14, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

For information concerning the final rule as it relates to devices regulated by the Center for Biologics Evaluation and Research: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

For information concerning the final rule as it relates to devices regulated by the Center for Devices and Radiological Health: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2438, Silver Spring, MD 20993–0002, 301–796–6524.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary
- A. Purpose of the Final Rule
- B. Summary of the Major Provisions of the Final Rule
- C. Legal Authority
- D. Costs and Benefits

II. Background
- A. Need for the Regulation
- B. History of the Rulemaking
- C. Summary of Comments to the Proposed Rule

III. Legal Authority
IV. Comments on the Proposed Rule and FDA Response
- A. Introduction
- B. Specific Comments and FDA Response
- C. Comments Outside the Scope of This Rulemaking

V. Effective Date
VI. Economic Analysis of Impacts
VII. Analysis of Environmental Impact
VIII. Paperwork Reduction Act of 1995
IX. Federalism
X. Consultation and Coordination With Indian Tribal Governments
XI. Reference

I. Executive Summary

A. Purpose of the Final Rule

FDA is amending its medical device regulations regarding the procedures for the announcement of approvals and denials of PMAs and HDEs to discontinue the quarterly publication in the **Federal Register** of a list of approvals and denials of both PMAs and HDEs. FDA will continue to post approval and denial notices for PMAs and HDEs on FDA's home page on the internet (*https://www.fda.gov*) and will also continue to make available on the internet and place on public display SSED for PMAs and SSPB for HDEs. FDA is taking this action to improve the efficiency of announcing approvals and denials of PMAs and HDEs and eliminate duplication in the current process for announcing this information. We are also updating Agency contact information and statutory references in certain PMA and HDE regulations for purposes of accuracy, clarity, and consistency.

B. Summary of the Major Provisions of the Final Rule

FDA is amending its regulations regarding the announcement procedures for the approval and denial of PMAs and HDEs. FDA is discontinuing publishing in the **Federal Register** after each quarter a list of PMA and HDE approvals and denials announced for that quarter. We will continue to post approval and denial notices for PMAs and HDEs on FDA's home page on the internet, and we will also continue to make SSED for PMAs and SSPB for HDEs available on the internet and place them on public display.

C. Legal Authority

FDA is issuing this final rule under sections 515, 520(h), 520(m), and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e, 360j(h), 360j(m), and 371(a)).

D. Costs and Benefits

The benefit of this final rule is that it will result in cost savings to FDA from discontinuing publishing in the **Federal Register**, on a quarterly basis, a list of medical device PMA and HDE approvals and denials. Annualized over 10 years, the estimated benefits (*i.e.,* cost savings) to FDA range from $0.008 million to $0.013 million at both 3 and 7 percent discount rate, with a primary estimate of $0.010 million. We estimate that this final rule will result in no additional costs to industry because the