[1] This National Oceanic and Atmospheric Administration maximum civil monetary penalty, as prescribed by law, is the maximum civil monetary penalty per 16 U.S.C. 1858(a), Magnuson-Stevens Fishery Conservation and Management Act civil monetary penalty (paragraph (f)(15) of this section).

[2] See footnote 1.

[3] See footnote 1.

[4] See footnote 1.

[5] See footnote 1.

[6] See footnote 1.

[7] See footnote 1.

[8] See footnote 1.

[9] See footnote 1.

[10] See footnote 1.

[11] See footnote 1.

[12] See footnote 1.

[13] See footnote 1.

[14] See footnote 1.

[15] See footnote 1.

[16] See footnote 1.

[17] See footnote 1.

[18] See footnote 1.

[19] See footnote 1.

§ 6.4 Effective date of adjustments for inflation to civil monetary penalties.

The Department of Commerce's 2023 adjustments for inflation made by § 6.3, of the civil monetary penalties there specified, are effective on January 15, 2023, and said civil monetary penalties, as thus adjusted by the adjustments for inflation made by § 6.3, apply only to those civil monetary penalties, including those whose associated violation predated such adjustment, which are assessed by the Department of Commerce after the effective date of the new civil monetary penalty level, and before the effective date of any future adjustments for inflation to civil monetary penalties thereto made subsequent to January 15, 2023 as provided in § 6.5.

§ 6.5 Subsequent annual adjustments for inflation to civil monetary penalties.

The Secretary of Commerce or his or her designee by regulation shall make subsequent adjustments for inflation to the Department of Commerce's civil monetary penalties annually, which shall take effect not later than January 15, notwithstanding section 553 of title 5, United States Code.

[FR Doc. 2022–28363 Filed 12–30–22; 8:45 am]

BILLING CODE 3510–DP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2000–N–0011]

Uniform Compliance Date for Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is establishing January 1, 2026, as the uniform compliance date for food labeling regulations that are published on or after January 1, 2023, and on or before December 31, 2024. We periodically announce uniform compliance dates for new food labeling requirements to minimize the economic impact of labeling changes.

DATES: This rule is effective January 3, 2023. Either electronic or written comments on the final rule must be submitted by March 6, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 6, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2000–N–0011 for ''Uniform Compliance Date for Food Labeling Regulations.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• 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.'' We will review this copy, including the claimed confidential information, in our 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 Dockets Management Staff. 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.govinfo.gov/content/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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We periodically issue regulations requiring changes in the labeling of food. If the compliance dates of these labeling changes were not coordinated, the cumulative economic impact on the food industry of having to respond separately to each change would be substantial. Therefore, we periodically have announced uniform compliance dates for new food labeling requirements (see *e.g.,* the **Federal Register** of October 19, 1984 (49 FR 41019); December 24, 1996 (61 FR 67710); December 27, 1996 (61 FR 68145); December 23, 1998 (63 FR 71015); November 20, 2000 (65 FR 69666); December 31, 2002 (67 FR 79851); December 21, 2006 (71 FR 76599); December 8, 2008 (73 FR 74349); December 15, 2010 (75 FR 78155); November 28, 2012 (77 FR 70885); December 10, 2014 (79 FR 73201); November 25, 2016 (81 FR 85156); December 20, 2018 (83 FR 65294); and January 6, 2021 (86 FR 462)). Use of a uniform compliance date provides for an orderly and economical industry adjustment to new labeling requirements by allowing sufficient lead time to plan for the use of existing label inventories and the development of new labeling materials.

II. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) 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.

III. Paperwork Reduction Act of 1995

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

IV. 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 establishment of a uniform compliance date does not in itself lead to costs or benefits. We will assess the costs and benefits of the uniform compliance date in the regulatory impact analyses of the labeling rules that take effect at that date.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule does not impose compliance costs on small entities, 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 $165 million, using the most current (2021) 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.

V. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have 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 have concluded 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.

VI. Conclusion

This action is not intended to change existing requirements for compliance dates contained in final rules published before January 1, 2023. Therefore, all final rules published by FDA in the **Federal Register** before January 1, 2023, will still go into effect on the date stated in the respective final rule. We generally encourage industry to comply with new labeling regulations as quickly as feasible, however. Thus, when industry members voluntarily change their labels, it is appropriate that they incorporate any new requirements that have been published as final regulations up to that time.

In rulemaking that began with publication of a proposed rule on April 15, 1996 (61 FR 16422), and ended with a final rule on December 24, 1996 (61 FR 67710) (together ''the 1996 rulemaking''), we provided notice and an opportunity for comment on the practice of establishing uniform compliance dates by issuance of a final rule announcing the date. We received

no comments objecting to this practice during the 1996 rulemaking, nor have we received comments objecting to this practice since we published a uniform compliance date final rule on January 6, 2021 (86 FR 462). (To the contrary, of the four comments received to the docket in 2021, only two comments that addressed our practice of issuing final rules announcing uniform compliance dates, and both comments expressed general support.) Therefore, we find good cause to dispense with issuance of a proposed rule inviting comment on the practice of establishing the uniform compliance date because such prior notice and comment are unnecessary. Interested parties will have an opportunity to comment on the compliance date for each individual food labeling regulation as part of the rulemaking process for that regulation. Consequently, FDA finds any further advance notice and opportunity for comment unnecessary for establishment of the uniform compliance date. Nonetheless, under 21 CFR 10.40(e)(1), we are providing an opportunity for comment on whether the uniform compliance date established by this final rule should be modified or revoked.

In addition, we find good cause for this final rule to become effective on the date of publication of this action. A delayed effective date is unnecessary in this case because the establishment of a uniform compliance date does not impose any new regulatory requirements on affected parties. Instead, this final rule provides affected parties with notice of our policy to identify January 1, 2026, as the compliance date for final food labeling regulations that require changes in the labeling of food products and that publish on or after January 1, 2023, and on or before December 31, 2024, unless special circumstances justify a different compliance date. Thus, affected parties do not need time to prepare before the rule takes effect. Therefore, we find good cause for this final rule to become effective on the date of publication of this action.

The new uniform compliance date will apply only to final FDA food labeling regulations that require changes in the labeling of food products and that publish on or after January 1, 2023, and on or before December 31, 2024. Those regulations will specifically identify January 1, 2026, as their compliance date. All food products subject to the January 1, 2026, compliance date must comply with the appropriate regulations when initially introduced into interstate commerce on or after January 1, 2026. If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2026, we will determine for that regulation an appropriate compliance date, which will be specified when the final regulation is published.

Dated: December 16, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–27902 Filed 12–30–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2022–N–3207]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Gastrointestinal Lesion Software Detection System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the gastrointestinal lesion software detection system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the gastrointestinal lesion software detection system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective January 3, 2023. The classification was applicable on April 9, 2021.

FOR FURTHER INFORMATION CONTACT: Pramodh Kariyawasam, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2536, Silver Spring, MD 20993–0002, 301–348–1911, *Pramodh.Kariyawasam@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the gastrointestinal lesion software detection system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.