suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration's definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). Individuals and states are not included in the definition of a small entity. This annual notice announces the Medicare Part A premiums for CY 2021 and will have an impact on certain Medicare beneficiaries. As a result, we are not preparing an analysis for the RFA because the Secretary has determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This annual notice announces the Medicare Part A premiums for CY 2021 and will have an impact on certain Medicare beneficiaries. As a result, we are not preparing an analysis for section 1102(b) of the Act, because the Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This notice does not impose mandates that will have a consequential effect of $156 million or more on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This notice will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have Federalism implications.

Executive Order 13771, titled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this notice is a transfer notice that does not impose more than de minimis costs and thus is not a regulatory action for the purposes of E.O. 13771.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

C. Congressional Review

Consistent with the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), this notice has been transmitted to the Congress and the Comptroller General for review.

Dated: October 30, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 2, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–25028 Filed 11–6–20; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8074–N]

RIN 0938–AU14

Medicare Program; CY 2021 Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year (CY) 2021 under Medicare's Hospital Insurance Program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts. For CY 2021, the inpatient hospital deductible will be $1,484. The daily coinsurance amounts for CY 2021 will be: $371 for the 61st through 90th day of hospitalization in a benefit period; $742 for lifetime reserve days; and $185.50 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period.

DATES: The deductible and coinsurance amounts announced in this notice are effective on January 1, 2021.

FOR FURTHER INFORMATION CONTACT:

Yaminee Thaker, (410) 786 7921 for general information.

Gregory J. Savord, (410) 786 1521 for case mix analysis.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1813 of the Social Security Act (the Act) provides for an inpatient hospital deductible to be subtracted from the amount payable by Medicare for inpatient hospital services furnished to a beneficiary. It also provides for certain coinsurance amounts to be subtracted from the amounts payable by Medicare for inpatient hospital and extended care services. Section 1813(b)(2) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) to determine and publish each year the amount of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts applicable for services furnished in the following calendar year (CY).

II. Computing the Inpatient Hospital Deductible for CY 2021

Section 1813(b) of the Act prescribes the method for computing the amount of the inpatient hospital deductible. The inpatient hospital deductible is an amount equal to the inpatient hospital deductible for the preceding CY, adjusted by our best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1886(b)(3)(B) of the Act) used for updating the payment rates to hospitals for discharges in the fiscal year (FY) that begins on October 1 of the same preceding CY, and adjusted to reflect changes in real case-mix. The adjustment to reflect real case-mix is determined on the basis of the most recent case-mix data available. The amount determined under this formula is rounded to the nearest multiple of $4 (or, if midway between two multiples of $4, to the next higher multiple of $4).

Under section 1886(b)(3)(B)(i)(XX) of the Act, the percentage increase used to update the payment rates for FY 2021 for hospitals paid under the inpatient prospective payment system is the market basket percentage increase, otherwise known as the market basket update, reduced by an adjustment based on changes in the economy-wide productivity (the multifactor productivity (MFP) adjustment) (see section 1886(b)(3)(B)(xi)(II) of the Act). Under section 1886(b)(3)(B)(viii) of the Act, for FY 2021, the applicable percentage increase for hospitals that do not submit quality data as specified by the Secretary is reduced by one quarter

of the market basket update. We are estimating that after accounting for those hospitals receiving the lower market basket update in the payment-weighted average update, the calculated deductible will not be affected, since the majority of hospitals submit quality data and receive the full market basket update. Section 1886(b)(3)(B)(ix) of the Act requires that any hospital that is not a meaningful electronic health record (EHR) user (as defined in section 1886(n)(3) of the Act) will have three-quarters of the market basket update reduced by 100 percent for FY 2017 and each subsequent FY. We are estimating that after accounting for these hospitals receiving the lower market basket update, the calculated deductible will not be affected, since the majority of hospitals are meaningful EHR users and are expected to receive the full market basket update.

Under section 1886 of the Act, the percentage increase used to update the payment rates (or target amounts, as applicable) for FY 2021 for hospitals excluded from the inpatient prospective payment system is as follows:

- The percentage increase for long term care hospitals is the market basket percentage increase reduced by the MFP adjustment (see section 1886(m)(3)(A) of the Act). In addition, these hospitals may also be impacted by the quality reporting adjustments and the site-neutral payment rates (see sections 1886(m)(5) and 1886(m)(6) of the Act).
- The percentage increase for inpatient rehabilitation facilities is the market basket percentage increase reduced by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act. In addition, these hospitals may also be impacted by the quality reporting adjustments (see section 1886(j)(7) of the Act).
- The percentage increase used to update the payment rate for inpatient psychiatric facilities is the market basket percentage increase reduced by the MFP adjustment (see section 1886(s)(2)(A)(i) of the Act). In addition, these hospitals may also be impacted by the quality reporting adjustments (see section 1886(s)(4) of the Act).
- The percentage increase used to update the target amounts for other types of hospitals that are excluded from the inpatient prospective payment system and that are paid on a reasonable cost basis, subject to a rate-of-increase ceiling, is the inpatient prospective payment system operating market basket percentage increase, which is described at section 1886(b)(3)(B)(ii)(VIII) of the Act and 42 CFR 413.40(c)(3). These other types of hospitals include cancer hospitals, children's hospitals, extended neoplastic disease care hospitals, and hospitals located outside the 50 states, the District of Columbia, and Puerto Rico.

The inpatient prospective payment system market basket percentage increase for FY 2021 is 2.4 percent and the MFP adjustment is 0.0 percentage point, as announced in the final rule that appeared in the **Federal Register** on September 18, 2020 entitled, ''Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Final Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals'' (85 FR 58432). Therefore, the percentage increase for hospitals paid under the inpatient prospective payment system that submit quality data and are meaningful EHR users is 2.4 percent (that is, the FY 2021 market basket update of 2.4 percent less the MFP adjustment of 0.0 percentage point). The average payment percentage increase for hospitals excluded from the inpatient prospective payment system is 2.34 percent. This average includes long term care hospitals, inpatient rehabilitation facilities, and other hospitals excluded from the inpatient prospective payment system. Weighting these percentages in accordance with payment volume, our best estimate of the payment-weighted average of the increases in the payment rates for FY 2021 is 2.39 percent.

To develop the adjustment to reflect changes in real case-mix, we first calculated an average case-mix for each hospital that reflects the relative costliness of that hospital's mix of cases compared to those of other hospitals. We then computed the change in average case-mix for hospitals paid under the Medicare inpatient prospective payment system in FY 2020 compared to FY 2019. (We excluded from this calculation hospitals whose payments are not based on the inpatient prospective payment system because their payments are based on alternate prospective payment systems or reasonable costs.) We used Medicare bills from prospective payment hospitals that we received as of July 2020. These bills represent a total of about 6.1 million Medicare discharges for FY 2020 and provide the most recent case-mix data available at this time. Based on these bills, the change in average case-mix in FY 2020 is 2.8 percent. Based on these bills and past experience, we expect the overall case mix change to be 3.8 percent as the year progresses and more FY 2020 data become available.

Section 1813 of the Act requires that the inpatient hospital deductible be adjusted only by that portion of the case-mix change that is determined to be real. Real case-mix is that portion of case-mix that is due to changes in the mix of cases in the hospital and not due to coding optimization. COVID–19 has complicated the determination of real case-mix increase. COVID–19 cases typically have higher-weighted MS–DRGs which would cause a real increase in case-mix while hospitals have experienced a reduction in lower-weighted cases which would also cause a real increase in case-mix. We compared the average case-mix for February 2020 through July 2020 (COVID–19 period) with average case-mix for October 2019 through January 2020 (pre-COVID–19 period). Since this increase applies for only a portion of CY 2020, we allocated this increase by the estimated discharges over the 2 periods—a 2.5 percent increase for FY 2020. The 1.3-percent residual case-mix increase is a mixture of real case-mix and coding optimization. Over the past several years, we have observed total case mix increases of about 0.5 percent per year and have assumed that they are real. Thus, since we do not have further information at this time, we expect that 0.5 percent of the residual 1.3 percent change in average case-mix for FY 2020 will be real. The combination of the 2.5-percent COVID–19 effect and the remaining residual 0.5-percent real case-mix increase is a 3.0-percent increase in real case-mix for FY 2020. Note that all case-mix calculations do not include the extra 20 percent adjustment in the MS–DRG relative weights for COVID–19 cases. The extra 20-percent adjustment is a payment artifact that should not be included in the measurement of case-mix.

Thus, the estimate of the payment-weighted average of the applicable percentage increases used for updating the payment rates is 2.39 percent, and the real case-mix adjustment factor for the deductible is 3.0 percent. Therefore, using the statutory formula as stated in section 1813(b) of the Act, we calculate the inpatient hospital deductible for services furnished in CY 2021 to be $1,484. This deductible amount is determined by multiplying $1,408 (the inpatient hospital deductible for CY 2020 (84 FR 61619)) by the payment-weighted average increase in the payment rates of 1.0239 multiplied by the increase in real case-mix of 1.03, which equals $1,484.90 and is rounded to $1,484.

III. Computing the Inpatient Hospital and Extended Care Services Coinsurance Amounts for CY 2021

The coinsurance amounts provided for in section 1813 of the Act are defined as fixed percentages of the inpatient hospital deductible for services furnished in the same CY. The increase in the deductible generates increases in the coinsurance amounts. For inpatient hospital and extended care services furnished in CY 2021, in accordance with the fixed percentages defined in the law, the daily coinsurance for the 61st through 90th day of hospitalization in a benefit period will be $371 (one-fourth of the inpatient hospital deductible as stated in section 1813(a)(1)(A) of the Act); the daily coinsurance for lifetime reserve days will be $742 (one-half of the inpatient hospital deductible as stated in section 1813(a)(1)(B) of the Act); and the daily coinsurance for the 21st through 100th day of extended care services in a skilled nursing facility (SNF) in a benefit period will be $185.50 (one-eighth of the inpatient hospital deductible as stated in section 1813(a)(3) of the Act).

IV. Cost to Medicare Beneficiaries

The Table below summarizes the deductible and coinsurance amounts for CYs 2020 and 2021, as well as the number of each that is estimated to be paid.

PART A DEDUCTIBLE AND COINSURANCE AMOUNTS FOR CALENDAR YEARS 2020 AND 2021

Type of cost sharing	Value		Number paid (in millions)	
	2020	2021	2020	2021
Inpatient hospital deductible	$1,408	$1,484	5.81	6.45
Daily coinsurance for 61st–90th Day	352	371	1.31	1.46
Daily coinsurance for lifetime reserve days	704	742	0.65	0.72
SNF coinsurance	176.00	185.50	28.82	32.19

The estimated total increase in costs to beneficiaries is about $2,450 million (rounded to the nearest $10 million) due to: (1) The increase in the deductible and coinsurance amounts; and (2) the increase in the number of deductibles and daily coinsurance amounts paid. We determine the increase in cost to beneficiaries by calculating the difference between the 2020 and 2021 deductible and coinsurance amounts multiplied by the estimated increase in the number of deductible and coinsurance amounts paid.

V. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment prior to a rule taking effect in accordance with section 1871 of the Act and section 553(b) of the Administrative Procedure Act (APA). Section 1871(a)(2) of the Act provides that no rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under Medicare shall take effect unless it is promulgated through notice and comment rulemaking. Unless there is a statutory exception, section 1871(b)(1) of the Act generally requires the Secretary to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment before establishing or changing a substantive legal standard regarding the matters enumerated by the statute. Similarly, under 5 U.S.C. 553(b) of the APA, the agency is required to publish a notice of proposed rulemaking in the **Federal Register** before a substantive rule takes effect. Section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act usually require a 30-day delay in effective date after issuance or publication of a rule, subject to exceptions. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the advance notice and comment requirement and the delay in effective date requirements. Sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act also provide exceptions from the notice and 60-day comment period and the 30-day delay in effective date. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act expressly authorize an agency to dispense with notice and comment rulemaking for good cause if the agency makes a finding that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest.

The annual inpatient hospital deductible and the hospital and extended care services coinsurance amounts announcement set forth in this notice does not establish or change a substantive legal standard regarding the matters enumerated by the statute or constitute a substantive rule which would be subject to the notice requirements in section 553(b) of the APA. However, to the extent that an opportunity for public notice and comment could be construed as required for this notice, we find good cause to waive this requirement.

Section 1813(b)(2) of the Act requires publication of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts between September 1 and September 15 of the year preceding the year to which they will apply. Further, the statute requires that the agency determine and publish the inpatient hospital deductible and hospital and extended care services coinsurance amounts for each CY in accordance with the statutory formulae, and we are simply notifying the public of the changes to the deductible and coinsurance amounts for CY 2021. We have calculated the inpatient hospital deductible and hospital and extended care services coinsurance amounts as directed by the statute; the statute establishes both when the deductible and coinsurance amounts must be published and the information that the Secretary must factor into the deductible and coinsurance amounts, so we do not have any discretion in that regard. We find notice and comment procedures to be unnecessary for this notice and we find good cause to waive such procedures under section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act, if such procedures may be construed to be required at all. Through this notice, we are simply notifying the public of the updates to the inpatient hospital deductible and the hospital and extended care services coinsurance amounts, in accordance with the statute, for CY 2021. As such, we also note that even if notice and comment procedures were required for this notice, for the reasons stated above, we would find good cause to waive the delay in

effective date of the notice, as additional delay would be contrary to the public interest under section 1871(e)(1)(B)(ii) of the Act. Publication of this notice is consistent with section 1813(b)(2) of the Act, and we believe that any potential delay in the effective date of the notice, if such delay were required at all, could cause unnecessary confusion both for the agency and Medicare beneficiaries.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VII. Regulatory Impact Analysis

Although this notice does not constitute a substantive rule, we nevertheless prepared this Regulatory Impact Analysis section in the interest of ensuring that the impacts of this notice are fully understood.

A. Statement of Need

Section 1813(b)(2) of the Act requires the Secretary to publish, between September 1 and September 15 of each year, the amounts of the inpatient hospital deductible and hospital and extended care services coinsurance applicable for services furnished in the following CY.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Although we do not consider this notice to constitute a substantive rule, this notice is economically significant under section 3(f)(1) of Executive Order 12866. As stated in section IV of this notice, we estimate that the total increase in costs to beneficiaries associated with this notice is about $2,450 million due to: (1) The increase in the deductible and coinsurance amounts; and (2) the increase in the number of deductibles and daily coinsurance amounts paid.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration's definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). Individuals and states are not included in the definition of a small entity. This annual notice announces the Medicare Part A deductible and coinsurance amounts for CY 2021 and will have an impact on the Medicare beneficiaries. As a result, we are not preparing an analysis for the RFA because the Secretary has determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This annual notice announces the Medicare Part A deductible and coinsurance amounts for CY 2021 and will have an impact on the Medicare beneficiaries. As a result, we are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This notice does not impose mandates that will have a consequential effect of $156 million or more on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This notice will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have Federalism implications.

Executive Order 13771, titled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this notice is a transfer notice that does not impose more than de minimis costs and thus is not a regulatory action for the purposes of E.O. 13771.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

C. Congressional Review

Consistent with the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), this notice has been transmitted to the Congress and the Comptroller General for review.

Dated: October 30, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 2, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–25024 Filed 11–6–20; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0530]

Voluntary Disclosure of Sesame as an Allergen: Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Voluntary Disclosure of Sesame as an Allergen.'' The draft guidance, when finalized, will provide food manufacturers with FDA's current views on sesame as an allergen and will provide recommendations to voluntarily disclose sesame in certain circumstances where such disclosure is not currently required. The guidance is intended to help individuals who are allergic to sesame identify those foods that may contain sesame as an ingredient. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by January 11, 2021 to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by January 11, 2021.

ADDRESSES: You may submit comments on any guidance at any time 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):* 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–2020–D–0530 for ''Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Nutrition and Food Labeling, Food Labeling and Standards Staff, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: *With regard to the draft guidance:* Carol D'lima, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Voluntary Disclosure of Sesame as an Allergen.'' We are issuing this draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person