

Steven Chadwick James (“Respondents”). The proposed consent order has been placed on the public record for 30 days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreement and the comments received and decide whether it should withdraw from the agreement or make final the agreement’s proposed order.

This matter involves Respondents’ labeling and advertising of motorcycle, motocross, and all-terrain vehicle products as “Made in USA.” According to the FTC’s complaint, Respondents labeled and advertised their products as made in the United States even though, in numerous instances, those products were wholly imported or contained significant imported content. Based on the foregoing, the complaint alleges Respondents violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45(a), and section 323.2 of the Made in USA Labeling Rule, 16 CFR 323.2.

The proposed consent order contains provisions designed to prevent Respondents from engaging in similar acts and practices in the future. Consistent with the FTC’s Made in USA Labeling Rule, 16 CFR part 323, and its Enforcement Policy Statement on U.S.-Origin Claims, Part I prohibits Respondents from making U.S.-origin claims for their products unless: (1) the final assembly or processing of the product occurs in the United States, all significant processing that goes into the product occurs in the United States, and all or virtually all ingredients or components of the product are made and sourced in the United States; (2) a clear and conspicuous qualification appears immediately adjacent to the representation that accurately conveys the extent to which the product contains foreign parts, ingredients or components, and/or processing; or (3) for a claim that a product is assembled in the United States, the product is last substantially transformed in the United States, the product’s principal assembly takes place in the United States, and United States assembly operations are substantial. Part II prohibits Respondents from making any representation about the country of origin of a product or service, unless the representation is not misleading and Respondents have a reasonable basis substantiating it.

Parts III through V are monetary provisions. Part IV imposes a judgment of \$872,577 and partially suspends that judgment based on the Respondents’

sworn financial statements. If the Commission concludes any Respondent made a material misrepresentation or omission in that Respondent’s sworn financial statement, the suspension as to that Respondent is lifted and the full judgment is immediately due. Part IV includes additional monetary provisions relating to collections. Part V requires Respondents to provide sufficient customer information to enable the Commission to administer consumer redress, if appropriate.

Part VI is a notice provision requiring Respondents to identify and notify certain consumers of the FTC’s action within 30 days after the issuance of the order, or within 30 days of the consumer’s identification, if identified later. Respondents are also required to submit reports regarding their notification program.

Parts VII through VIII are reporting and compliance provisions. Part VII requires Respondents to acknowledge receipt of the order, to provide a copy of the order to certain current and future principals, officers, directors, and employees, and to obtain an acknowledgement from each such person that they have received a copy of the order. Part VIII requires Respondents to file a compliance report within one year after the order becomes final and to notify the Commission within 14 days of certain changes that would affect compliance with the order. Part IX requires Respondents to maintain certain records, including records necessary to demonstrate compliance with the order. Part X requires Respondents to submit additional compliance reports when requested by the Commission and to permit the Commission or its representatives to interview Respondents’ personnel.

Finally, Part XI is a “sunset” provision, terminating the order after 20 years, with certain exceptions.

The purpose of this analysis is to aid public comment on the Proposed Order. It is not intended to constitute an official interpretation of the complaint or Proposed Order, or to modify in any way the Proposed Order’s terms.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2023–08471 Filed 4–20–23; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10302]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by June 20, 2023.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10302 Collection Requirements for Compendia for Determination of Medically-accepted Indications for Off-label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Collection Requirements for Compendia for Determination of Medically-accepted Indications for Off-label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen; *Use:* Section 182(b) of the Medicare Improvement of Patients and Providers Act (MIPPA) amended section 1861(t)(2)(B) of the Social Security Act (42 U.S.C. 1395x(t)(2)(B)) by adding at the end the following new sentence: "On and after January 1, 2010, no compendia

may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest." We believe that the implementation of this statutory provision that compendia have a "publicly transparent process for evaluating therapies and for identifying potential conflicts of interests" is best accomplished by amending 42 CFR 414.930 to include the MIPPA requirements and by defining the key components of publicly transparent processes for evaluating therapies and for identifying potential conflicts of interests.

All currently listed compendia will be required to comply with these provisions, as of January 1, 2010, to remain on the list of recognized compendia. In addition, any compendium that is the subject of a future request for inclusion on the list of recognized compendia will be required to comply with these provisions. No compendium can be on the list if it does not fully meet the standard described in section 1861(t)(2)(B) of the Act, as revised by section 182(b) of the MIPPA. *Form Number:* CMS-10302 (OMB control number: 0938-1078); *Frequency:* Annually; *Affected Public:* Business and other for-profits and Not-for-profit institutions; *Number of Respondents:* 845; *Total Annual Responses:* 900; *Total Annual Hours:* 5,135. (For policy questions regarding this collection contact Sarah Fulton at 410-786-2749.)

Dated: April 17, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023-08401 Filed 4-20-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias (ADRD) on people with the disease and their caregivers. During the

meeting on May 8, 2023, the Advisory Council will hear presentations about the drug approval and coverage decision processes. A panel will also present on progress and challenges in translating research into clinical impact. Federal agencies will provide updates on activities during the last quarter.

DATES: The meeting will be held on May 8th from 9:30 p.m. to 4:30 p.m. EST.

ADDRESSES: The meeting will be a hybrid of in-person and virtual. The meeting will be held in Room 305A of the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. It will also stream live at www.hhs.gov/live.

Comments: Time is allocated on the agenda to hear public comments from 4:00 p.m. to 4:30 p.m. The time for oral comments will be limited to two (2) minutes per individual. In order to provide a public comment, please register by emailing your name to napa@hhs.gov by Thursday, May 4th. Registered commenters will receive both a dial-in number and a link to join the meeting virtually; individuals will have the choice to either join virtually via the link, or to call in only by using the dial-in number. *Note:* There may be a 30-45 second delay in the livestream video presentation of the conference. For this reason, if you have pre-registered to submit a public comment, it is important to connect to the meeting by 3:45 p.m. to ensure that you do not miss your name and allotted time when called. You will not be admitted into the meeting before 3:45 p.m. If you miss your name and allotted time to speak, you may not be able to make your public comment. Should you have questions during the session email napa@hhs.gov and someone will respond to your message as quickly as possible.

In order to ensure accuracy, please submit a written copy of oral comments for the record by emailing napa@hhs.gov by Tuesday, May 9, 2023. These comments will be shared on the website and reflected in the meeting minutes.

In lieu of oral comments, formal written comments may be submitted for the record by Tuesday, May 9, 2023 to Helen Lamont, Ph.D., OASPE, 200 Independence Avenue SW, Room 424E, Washington, DC 20201. Comments may also be sent to napa@hhs.gov. Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Helen Lamont, 202-260-6075, helen.lamont@hhs.gov. *Note:* The meeting will be available to the public live at www.hhs.gov/live. *Note:* Seating