DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–3699]

Determination That IC-GREEN (Indocyanine Green), 25 Milligrams/Vial, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that IC-GREEN (indocyanine green), 25 milligrams (mg)/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for IC-GREEN (indocyanine green), 25 mg/vial, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Madeleine Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, *Madeleine.Giaquinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

IC-GREEN (indocyanine green), 25 mg/vial, is the subject of NDA 11525, held by Renew Pharmaceuticals and initially approved on February 9, 1959. IC-GREEN, 25 mg/vial, is indicated for determining cardiac output, hepatic function, and liver blood flow.

IC-GREEN (indocyanine green), 25 mg/vial, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Zydus Pharmaceuticals (USA), Inc. submitted a citizen petition dated August 2, 2024 (Docket No. FDA–2024–P–3699), under 21 CFR 10.30, requesting that the Agency determine whether IC-GREEN (indocyanine green), 25 mg/vial, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that IC-GREEN (indocyanine green), 25 mg/vial, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of IC-GREEN (indocyanine green), 25 mg/vial, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list IC-GREEN (indocyanine green), 25 mg/vial, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to this drug product or these drug products may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 7, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–27090 Filed 11–19–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3110]

Miguel Angel Montalvo Villa: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Miguel Angel Montalvo Villa from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Montalvo Villa was convicted of multiple felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Mr. Montalvo Villa was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of September 19, 2024 (30 days after receipt of the notice), Mr. Montalvo Villa has not responded. Mr. Montalvo Villa's failure to respond and request a hearing constitutes a waiver of Mr. Montalvo Villa's right to a hearing concerning this matter.

DATES: This order is applicable November 20, 2024.

ADDRESSES: Any application by Mr. Montalvo Villa for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted at any time as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov.*

• If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

• *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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2024–N–3110. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. 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. 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, 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 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, 240–402–8743, or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product. On November 30, 2023, Mr. Montalvo Villa was convicted as defined in section 306(l)(1) of the FD&C Act in the U. S. District Court for the Southern District of Florida-Miami Division when the court entered judgment against him, after a jury trial, for three offenses, one count of conspiracy to commit wire fraud in violation of 18 U.S.C. 1349, one count of wire fraud in violation of 18 U.S.C. 1343, and one count of false statements in violation of 18 U.S.C. 1001(a)(2). The underlying facts supporting the conviction are as follows: as contained in the witness testimony reflected in the transcripts from Mr. Montalvo Villa's trial, from around January 2015, through about March 2018, Mr. Montalvo Villa was the co-owner of AMB Research Center, Inc. (AMB), a medical clinic located in Miami, Florida. AMB conducted clinical trials of new drugs for pharmaceutical companies and other sponsors. At AMB, Mr. Montalvo Villa was the majority owner and served as President. In March 2016, AMB entered into a Clinical Trial Agreement with a Contract Research Organization (CRO) that managed and oversaw a clinical trial designed to evaluate the safety and efficacy of an investigational drug intended to treat persons with Clostridium difficile-associated diarrhea (CDAD clinical trial) on behalf of a sponsor (a pharmaceutical company).

Mr. Montalvo Villa, along with his co-conspirators, entered into a conspiracy to cause the sponsor and/or the CRO to make payments on the contracts for the CDAD clinical trial, by making false and fraudulent representations regarding, among other things, subject eligibility for and participation in the CDAD clinical trial, and falsifying and fabricating documents, data, and other items relating to the CDAD clinical trial including subject informed consent forms, case histories, and data.

Mr. Montalvo Villa participated with two other co-conspirators with falsifying and fabricating study documents. Mr. Montalvo Villa and his co-conspirators falsified the study data of subjects who did not participate in the CDAD clinical trial in full compliance with the protocol. Mr. Montalvo Villa was primarily responsible in completing the patients' informed consent form and falsifying their signatures to make it appear as though the patients had consented to participate in the clinical trial when they had not.

For purposes of obtaining money from the sponsor and/or CRO, Mr. Montalvo Villa along with his co-conspirators, created false and fraudulent study records and submitted fraudulent stool and blood samples. For example, electronic case record files (eCRFs) falsely represented that the subjects completed the informed consent form (ICF) process with the Principal Investigator which required her to review the ICF with each subject and personally obtain the subject's written informed consent. In fact, she never completed the ICF process with subjects, and some subjects had never been to AMB or did not participate in the trial. Mr. Montalvo Villa knew that false information and data was submitted in the case report forms and eCRFs including false information and data representing that subjects had satisfied eligibility criteria to participate in the CDAD clinical trial, received and taken the study medication, provided stool samples, completed the required documents and journals, and participated in assessments conducted by the clinical investigator. In addition, Mr. Montalvo Villa knew that 10 or more individuals' means of identification were used unlawfully or without authority in furtherance of the conspiracy. Specifically, Mr. Montalvo Villa, along with some of his co-conspirators, used the means of identification of real persons, to create subject identification numbers for those persons, and then used those subject identification numbers to falsely portray

the persons as legitimate subjects in the CDAD clinical trial, when in fact they were not. Mr. Montalvo Villa was primarily responsible for completing the patients' informed consent form and falsifying their signatures to make it appear as though the patients consented to participate in the clinical trial when they had not. In addition, Mr. Montalvo Villa along with his co-conspirators submitted his own stool and blood samples to make it appear as if they came from study participants.

Furthermore, Mr. Montalvo Villa was one of only two individuals who inputted CDAD clinical trial data in the Almac Clinical Technology Integrated Response Technology database (Almac database). The information in the Almac database was the foundation for all subsequent subject CDAD clinical trial data. Mr. Montalvo Villa repeatedly entered false and fabricated subject screening and randomization information in the Almac database.

After an on-site audit by the Sponsor of AMB, the Sponsor notified the FDA in writing of potential scientific misconduct by AMB. Mr. Montalvo Villa wrote AMB's response letter, which contained false information, for the Principal Investigator's signature. Mr. Montalvo Villa told the Principal Investigator that she would lose her medical license if she did not sign the letter. In addition, an FDA regulatory investigator conducted an official on-site inspection of AMB for the CDAD clinical trial that began on February 20, 2018. On the first day of the inspection, Mr. Montalvo Villa told the FDA investigator that during the CDAD clinical trial he was present when his co-conspirator, the Principal Investigator, had obtained all the informed consents from the trial subjects. Mr. Montalvo Villa also told the regulatory investigator that copies of the informed consent were given to the subjects and that he was the most responsible person at AMB.

Mr. Montalvo Villa received $100,634.84 in proceeds for the CDAD clinical trial. AMB received over $277,000 for the CDAD clinical trial.

FDA sent Mr. Montalvo Villa, by certified mail, on August 12, 2024, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) of the FD&C Act, that Mr. Montalvo Villa was convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product. The proposal informed Mr. Montalvo Villa of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Montalvo Villa received the proposal and notice of opportunity for a hearing on August 20, 2024. Mr. Montalvo Villa failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Division of Field Enforcement Director, finds that Mr. Miguel Angel Montalvo Villa has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product.

As a result of the foregoing finding, Mr. Montalvo Villa is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(A) and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Mr. Montalvo Villa during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Montalvo Villa provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Montalvo Villa during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262)'' (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Dated: November 7, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0150]

Revocation of Two Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Cue Health, Inc., for the Cue COVID–19 Test, and Cue COVID–19 Test for Home and Over The Counter (OTC) Use. FDA revoked the Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holder. The revocations, which include an explanation of the reasons for each revocation, are reprinted at the end of this document.

DATES: The revocation of the Authorizations for the Cue Health, Inc.'s Cue COVID–19 Test, and Cue COVID–19 Test for Home and Over The Counter (OTC) Use are effective as of October 9, 2024.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (this is not a toll-free number).