under authority delegated to the Director, Division of Enforcement, finds that Mrs. Angela Anatilde Baquero 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, Mrs. Baquero 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 Mrs. Baquero during her 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 Mrs. Baquero provides services in any capacity to a person with an approved or pending drug product application during her period of debarment, she 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 Mrs. Baquero during her 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))).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15635 Filed 7–31–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–1535]

Ricardo Andres Acuna: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Ricardo Andres Acuna 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 Ricardo Andres Acuna was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Mr. Acuna was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of May 6, 2026 (30 days after receipt of the notice), Mr. Acuna has not responded. Mr. Acuna's failure to respond and request a hearing constitutes a waiver of Mr. Acuna's right to a hearing concerning this matter.

DATES: This order is applicable August 3, 2026.

ADDRESSES: Any application by Mr. Acuna 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–2026–N–1535. 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. 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, 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 under the FD&C Act.

On January 14, 2026, Mr. Acuna 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, Fort Lauderdale Division, when the court accepted his plea of guilty and entered judgment against him for conspiracy to commit wire fraud against the United States in violation of 18 U.S.C. 371. The underlying facts supporting the conviction are as follows:

As contained in the Information and in the Factual Proffer in Support of Guilty Plea from Mr. Acuna's case, between about January 2019 and January 2020, Mr. Acuna conspired with others to defraud a pharmaceutical sponsor conducting clinical trials for asthma medications. As co-owner of A&R Research Group LLC (A&R) with his wife Angela Baquero, Mr. Acuna served as the regulatory and contract affairs manager, responsible for maintaining study documents, collecting signatures, completing required forms, and serving as the primary contact for sponsors. Mrs. Baquero acted as clinical research director and study coordinator of A&R which partnered with a licensed Florida physician who served as the clinical investigator for all trials.

A&R conducted two clinical trials for investigational asthma drugs, receiving $320,247.98 from the sponsor. Mr. Acuna signed Clinical Trial Agreements with the Contract Research Organization (CRO) representing the sponsor, acknowledging A&R's obligation to follow trial protocols and applicable Federal regulations. He also signed Site Delegation Authority Logs and received training from the CRO, demonstrating his knowledge of the requirements and his delegated responsibilities. Mr. Acuna understood that the sponsor, CRO, and FDA could audit the trial site at any time and that A&R was required to cooperate fully with auditors.

The conspiracy's purpose was to unlawfully enrich Mr. Acuna and his co-conspirators through two primary schemes: making false representations about subject eligibility and participation to secure payments from the sponsor and/or CRO, and falsifying material trial documents and data, including case histories, spirometry readings, echocardiogram data, and other data.

Mr. Acuna and his co-conspirators knowingly failed to conduct the trials according to the trial protocols and applicable federal regulations. Mrs. Baquero, along with Co-Conspirator 1 and Co-Conspirator 2, obtained fake medical records for at least 17 trial subjects who lacked legitimate documentation of qualifying asthma diagnoses. Mr. Acuna facilitated this fraud by issuing payments to the co-conspirators for obtaining these false records. For instance, on June 12, 2019, Mr. Acuna signed a check for $120 to Co-Conspirator 1 for fake medical records for two subjects.

The fraud extended beyond falsified enrollment documents. Mrs. Baquero directed Co-Conspirator 1 and Co-Conspirator 2 to perform spirometry readings and provide blood samples on behalf of other enrolled subjects, and Mr. Acuna issued payments for these fraudulent assessments. On May 28, 2019, Mr. Acuna signed a check for $150 to Co-Conspirator 2 for ''4 Spriometries,'' knowing this compensated the co-conspirator for performing tests on behalf of other subjects. Significantly, Mr. Acuna did not include this payment in any trial-related records. These fraudulent spirometry readings and blood samples were submitted to the CRO and sponsor to create the false impression that subjects were participating properly and that A&R was conducting the studies in accordance with the clinical trial protocols.

In August 2019, based in part on suspicious spirometry and echocardiogram readings, the sponsor conducted an in-person audit of A&R. During this audit, Mr. Acuna and Mrs. Baquero provided case histories that they knew contained records of payments to subjects who had not actually participated in the studies. On January 24, 2020, these same fraudulent case histories were provided to an FDA investigator during an official inspection. Through these false and fraudulent representations regarding the asthma trials, Mr. Acuna's conduct resulted in A&R receiving the full $320,247.98 payment from the sponsor, enriching both himself and Mrs. Baquero as joint owners and controllers of the company.

As a result of this conviction, FDA sent Mr. Acuna, by certified mail, on March 27, 2026, 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. Acuna 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. Acuna 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 a waiver of any contentions concerning this action. Mr. Acuna received the proposal and notice of opportunity for a hearing on April 6, 2026. Mr. Acuna 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 Director, Division of Enforcement, finds that Mr. Ricardo Andres Acuna 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. Acuna 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. Acuna 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. Acuna 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. Acuna 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))).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15636 Filed 7–31–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1254]

Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry titled ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs.'' This guidance provides recommendations for the design and conduct of studies evaluating the adhesion performance of a transdermal or topical delivery system (collectively referred to as TDS). Depending on the objectives of a generic TDS product development program, applicants may choose to evaluate TDS adhesion in studies performed to evaluate TDS adhesion only, or in studies performed with a combined purpose (*e.g.,* for the simultaneous evaluation of adhesion and bioequivalence (BE) with pharmacokinetic (PK) endpoints). The recommendations in this guidance relate to studies submitted in support of an abbreviated new drug application (ANDA). The guidance replaces the draft guidance (Revision 2) ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs,'' issued on April 13, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on August 3, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2016–D–1254 for ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs.'' 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.'' The Agency will review this copy, including the claimed confidential information, in its 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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Susan Levine, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1674, Silver Spring, MD 20993–0002, 240–402–7936, *Susan.Levine@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry titled ''Assessing Adhesion With Transdermal