

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Thomas Prevoznik,
Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1654]

Bulk Manufacturer of Controlled Substances Application: Scottsdale Research Institute

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Scottsdale Research Institute has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before April 14, 2026. Such persons may also file a written request for a hearing on the application on or before April 14, 2026.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on January 8, 2026, Scottsdale Research Institute, 12815 North Cave Creek Road, Phoenix,

Arizona 85022, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols ...	7370	I

The company plans to bulk manufacture the listed controlled substances to support clinical trials and distribution to their customers. No other activities for these drug codes are authorized for this registration.

Thomas Prevoznik,
Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

John Bender, M.D.; Decision and Order

On October 17, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to John Bender, M.D., of Fort Collins, Florida (Respondent). OSC/ISO, at 1. The OSC/ISO informed Respondent of the immediate suspension of his DEA Certificates of Registration Nos. BB3697577 and FB3064831, alleging that Respondent's continued registration is "an imminent danger to the public health or safety." *Id.* (quoting 21 U.S.C. 824(d)). The OSC also proposed the revocation of Respondent's registration because Respondent has committed such acts as would render his registration inconsistent with the public interest. *Id.* (citing 21 U.S.C. 823(g)(1); 824(a)(4)).

More specifically, the OSC alleges that between April 25, 2022, and June 11, 2024, Respondent filled approximately 4,244 controlled substance prescriptions issued by practitioners at his clinic without possessing a state pharmacy license or a DEA pharmacy registration, in violation of state and federal law. *Id.* at 4 (citing 21 CFR 1306.04 and 1306.06, and Colo. Rev. Stat. 12-280-120(1) and 12-280-129(1)(d)).^{1,2} The OSC further

¹ The Government further alleges that Respondent violated 21 CFR 1307.11 but does not reference this provision in its Post-Hearing Brief. See OSC, at 4. The OSC also alleges that Respondent failed to report prescriptions to the Colorado Prescription Monitoring Program but the Government does not reference these allegations in its Post-Hearing Brief.

alleges that the two office locations where Respondent dispensed controlled substances operated as unregistered pharmacies. *Id.* (citing 21 U.S.C. 823(g)(1), 21 CFR 1301.11(a), 1301.13(e), Colo. Rev. Stat 12-280-120(1), 12-280-129(1)(d)).

After conducting a hearing, Administrative Law Judge, Paul E. Soeffing issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (Recommended Decision or RD) on June 2, 2025. The RD recommended that the Agency revoke Respondent's registration. RD, at 32. Respondent filed untimely exceptions to the RD.³ The Agency adopts and hereby incorporates by reference the ALJ's credibility findings,⁴ findings of fact, sanctions analysis, and recommended sanction, and summarizes and clarifies portions

Id. at 3. Accordingly, the Agency considers these allegations as abandoned and does not address them.

² The Agency need not adjudicate the criminal violations alleged in the OSC/ISO. *Ruan v. United States*, 597 U.S. 450 (2022) (decided in the context of criminal proceedings).

³ Respondent's Exceptions were filed on July 28, 2025, over a month after the regulatory deadline of June 22, 2025. See 21 CFR 1316.66 (requiring Exceptions to be filed "[w]ithin twenty days after the date upon which a party is served a copy of the report of the presiding officer"); June 30, 2025 Transmittal Letter from the Chief ALJ (stating that the ALJ's Recommended Decision was sent to the parties on June 2, 2025). Respondent states in its Motion for Leave to File Exceptions Out of Time that "[u]nder 21 CFR 1316.66, a party may be granted leave to file exceptions out of time when it serves the interests of justice and the other party is not prejudiced." This is a misstatement of 21 CFR 1316.66, which outlines the foregoing standard for assessing whether a party may file a response to the opposing party's Exceptions after the 20-day deadline has lapsed. Here, the Government did not file Exceptions.

In the absence of a more specific standard for assessing the timeliness of Respondent's Exceptions, the Agency considers whether Respondent has provided good cause for the untimely filing, and finds that Respondent has not. Respondent did not provide any explanation for why his Exceptions were over a month late, why he did not request an extension from the ALJ, or why the late filing should be excused. July 17, 2025 Motion for Leave. Respondent simply argued that the interests of justice require his Exceptions to be considered because the ALJ's recommendations were incorrect, unsupported, and infringed upon his constitutional rights. *Id.* at 1-2. In other words, Respondent's justification for the late filing was that he disagreed with the Recommended Decision.

Notwithstanding Respondent's failure to demonstrate good cause, the Agency exercises its discretion to consider Respondent's untimely Exceptions, in part because the Agency has not adopted the ALJ's legal analysis and finds that addressing Respondent's Exceptions provides important guidance to the registrant community on DEA's interpretations of the relevant provisions of the CSA. Ultimately, the Agency rejects Respondent's Exceptions and agrees with the ALJ's recommended sanction.

⁴ The Agency adopts the ALJ's summary of each witness's testimony, as well as the ALJ's assessment of each witness's credibility. See RD, at 3-10.