June 9, 2026

SUBMITTED VIA CFTC PORTAL
Secretary of the Commission
Office of the Secretariat
U.S. Commodity Futures Trading Commission
Three Lafayette Centre
1155 21st Street, N.W.
Washington, D.C. 20581

Re: KalshiEX LLC – CFTC Regulation 40.2(a) Notification Regarding the Initial Listing of the "Will the FDA's decision on <drug> in <time period> be <outcome>?" Contract

Dear Sir or Madam,

Pursuant to Section 5c(c) of the Commodity Exchange Act and Section 40.2(a) of the regulations of the Commodity Futures Trading Commission, KalshiEX LLC (Kalshi), a registered DCM, hereby notifies the Commission that it is self-certifying the "Will the FDA's decision on <drug> in <time period> be <outcome>?" contract (Contract). The Contract will initially be listed after close-of-business on **June 10, 2026**; it is listed as the day after because of limitations of the Commission's online submission portal. The Exchange intends to list the contract on a custom basis. The Contract's terms and conditions (Appendix A) includes the following strike conditions:

- **<drug>**
- **<drug manufacturer>**
- **<time period>**
- **<outcome>**

Along with this letter, Kalshi submits the following documents:

- A concise explanation and analysis of the Contract;
- Certification;
- Appendix A with the Contract's Terms and Conditions;
- Confidential Appendices with further information; and
- A request for FOIA confidential treatment.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Xavier Sottile
Head of Markets
KalshiEX LLC
xsottile@kalshi.com

KalshiEX LLC
Official Product Name: "Will the FDA's decision on <drug> in <time period> be <outcome>?"
Rulebook: FDADECISION
Summary: FDA drug decisions
Kalshi Contract Category: Health/Science
Kalshi Internal Category: Health
June 9, 2026

CONCISE EXPLANATION AND ANALYSIS OF THE PRODUCT AND ITS COMPLIANCE WITH APPLICABLE PROVISIONS OF THE ACT, INCLUDING CORE PRINCIPLES AND THE COMMISSION'S REGULATIONS THEREUNDER

Pursuant to Commission Rule 40.2(a)(3)(v), the following is a concise explanation and analysis of the product and its compliance with the Act, including the relevant Core Principles (discussed in Appendix D), and the Commission's regulations thereunder.

I. Introduction

The "Will the FDA's decision on <drug> in <time period> be <outcome>?" Contract is a contract relating to **Health**.

Further information about the Contract, including an analysis of its risk mitigation and price basing utility, as well as additional considerations related to the Contract, is included in Confidential Appendices C, D, and E.

Pursuant to Section 5c(c) of the Act and CFTC Regulations 40.2(a), the Exchange hereby certifies that the listing of the Contract complies with the Act and Commission regulations under the Act.

General Contract Terms and Conditions: The Contract operates similar to other event contracts that the Exchange lists for trading. The minimum price fluctuation is $0.01 (one cent). Price bands will apply so that Contracts may only be listed at values of at least $0.01 and at most $0.99. Further, the Contract is sized with a one-dollar notional value and has a minimum price fluctuation of $0.01 to enable Members to match the size of the contracts purchased to their economic risks. As outlined in Rule 5.16 of the Rulebook, trading shall be available at all times outside of any maintenance windows, which will be announced in advance by the Exchange. Members will be charged fees in accordance with Rule 3.13 of the Rulebook. Fees, if they are charged, are charged in such amounts as may be revised from time to time to be reflected on the Exchange's Website. A new Source Agency can be added via a Part 40 amendment. All instructions on how to access the Underlying are non-binding and are provided for convenience only and are not part of

the binding Terms and Conditions of the Contract. They may be clarified at any time. Furthermore, the Contract's payout structure is characterized by the payment of an absolute amount to the holder of one side of the option and no payment to the counterparty. During the time that trading on the Contract is open, Members are able to adjust their positions and trade freely. The Expiration Value and Market Outcome are determined at or after Market Close. The market is then settled by the Exchange, and the long position holders and short position holders are paid according to the Market Outcome. In this case, "long position holders" refers to Members who purchased the "Yes" side of the Contract and "short position holders" refers to Members who purchased the "No" side of the Contract. If the Market Outcome is "Yes," meaning that an event occurs that is encompassed within the Payout Criterion, then the long position holders are paid an absolute amount proportional to the size of their position and the short position holders receive no payment. If the Market Outcome is "No," then the short position holders are paid an absolute amount proportional to the size of their position and the long position holders receive no payment. Specification of the circumstances that would trigger a Market Outcome of "Yes" are included below in the section titled "Payout Criterion" in Appendix A.

CERTIFICATIONS PURSUANT TO SECTION 5c OF THE COMMODITY EXCHANGE ACT, 7 U.S.C. § 7A-2 AND COMMODITY FUTURES TRADING COMMISSION RULE 40.2, 17 C.F.R. § 40.2

Based on the above analysis, the Exchange certifies that:

- ❏ The Contract complies with the Act and Commission regulations thereunder.
- ❏ This submission (other than those appendices for which confidential treatment has been requested) has been concurrently posted on the Exchange's website at https://kalshi.com/regulatory/filings.

Should you have any questions concerning the above, please contact the exchange at ProductFilings@kalshi.com.

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By: Xavier Sottile
Title: Head of Markets
Date: June 9, 2026

Attachments:

Appendix A - Contract Terms and Conditions
Appendix B - Trading Prohibitions
Appendix C (Confidential) - Further Considerations
Appendix D (Confidential) - Source Agency
Appendix E (Confidential) - Compliance with Core Principles

APPENDIX A – CONTRACT TERMS AND CONDITIONS

Official Product Name: "Will the FDA's decision on <drug> in <time period> be <outcome>?"
Rulebook: FDADECISION

FDADECISION

Scope: These rules shall apply to this contract.

Underlying: The Underlying for this Contract is the U.S. Food and Drug Administration's (FDA) disposition, in <time period>, of the marketing application for <drug>, as documented by the Source Agency. Revisions to the Underlying made after Expiration will not be accounted for in determining the Expiration Value.

Source Agency: The Source Agency is AppliedXL.

Type: The type of Contract is an Event Contract.

Issuance: After the initial Contract, Contract iterations will be listed on an as-needed basis at the discretion of the Exchange and corresponding to the risk management needs of Members.

<drug>: <drug> refers to a pharmaceutical product, biologic, vaccine, therapeutic, cellular or gene therapy, or combination product that is the subject of a marketing application before the FDA, as specified by the Exchange. <drug> may be identified by its International Nonproprietary Name or generic name (e.g., "lecanemab"), its proprietary or brand name (e.g., "Leqembi"), its development code or compound designation (e.g., "RP-L201"), an associated application number (e.g., an NDA, BLA, or supplement number), or an associated trial identifier (e.g., an NCT number). The Exchange may specify the indication or population at issue; where the Exchange specifies an indication, only an FDA decision on the application for that indication (or an indication encompassing it) shall be considered. Where the Exchange specifies no indication, any FDA decision on the marketing application for <drug> shall be considered. Where <drug> is renamed, rebranded, or reformulated in a manner that does not alter the active ingredient or application under review, the Contract continues to track the same application under its updated designation, as announced by the Exchange.

<drug manufacturer>: <drug manufacturer> refers to the applicant or sponsor of record for the marketing application for <drug>, as specified by the Exchange. <drug manufacturer> may be identified by its legal corporate name, a widely recognized trade name, or a ticker symbol, and includes any subsidiary, division, or wholly owned affiliate that is the applicant of record. The identity of <drug manufacturer> shall remain consistent throughout the life of the Contract. Where the application is transferred, or where <drug manufacturer> undergoes a name change, merger, or acquisition, the successor applicant of record shall be treated as <drug manufacturer>, and the Exchange will announce any such determination to Members pursuant to Rule 7.1.

<time period>: <time period> refers to a specific duration or range of time as specified by the Exchange. May be expressed as a calendar year (e.g., "2026"), a calendar month and year (e.g., "June 2026"), a calendar quarter (e.g., "Q2 2026"), a specific week, or other bounded time periods as appropriate to the Contract subject matter. All time periods are interpreted in Eastern Time (ET) unless otherwise specified. The end of <time period> is defined as 11:59:59 PM ET on the final day of the specified period unless otherwise specified. The Exchange may list iterations of the Contract corresponding to variations of <time period>.

<outcome>: <outcome> refers to a category of FDA regulatory disposition specified by the Exchange and listed as a strike of the Contract. The categories listed for a given Contract iteration are mutually exclusive and collectively exhaustive, such that exactly one <outcome> resolves Yes. Unless the Exchange specifies otherwise in the Contract listing, the listed categories are: "Full Approval," "Conditional / Accelerated Approval," "Denied (CRL Issued)," "Withdrawn by Sponsor," and "No Decision." Each category is defined in the Payout Criterion.

Payout Criterion: The Payout Criterion for the Contract encompasses the Expiration Values that the FDA's decision on <drug> in <time period> is <outcome>.

For the purposes of this Contract, the following definitions apply.

- An "approval" means the FDA's issuance of an approval letter for the marketing application for <drug>, including a New Drug Application (NDA), Biologics License Application (BLA), supplemental NDA or BLA (sNDA/sBLA), Abbreviated New Drug Application (ANDA), or 351(k) biosimilar application, whether granted through the standard (traditional) process or through the accelerated approval pathway.
- A "limited authorization" means any of the following FDA actions that permit some authorized use of <drug> short of a full standard marketing approval: (i) an Emergency Use Authorization or other authorization of an unapproved product; (ii) a tentative approval (e.g., an ANDA tentative approval where the application is found to meet approval requirements but final approval is barred by an unexpired patent or exclusivity); (iii) an FDA approval, license, or permission solely for export or for use outside the United States; or (iv) an authorization or grant solely under an expanded-access, compassionate-use, or right-to-try program.
- A "Complete Response Letter" (CRL) means a letter issued by the FDA stating that the application cannot be approved in its current form.
- A "withdrawal" means the applicant's formal withdrawal of the marketing application, effectuated before the FDA has taken final action (approval or CRL) on the then-current application.

The applicable <outcome> is determined by applying the following classification rules in order; the first rule whose condition is satisfied governs, and no subsequent rule applies:

- **(1) Full Approval.** If the FDA issues an approval for <drug> within <time period> (and, where the Exchange has specified an indication, for an indication that encompasses the specified indication), and that approval is not granted under, and is not expressly subject to, the FDA's accelerated/conditional approval pathways as described in the next bullet point, the <outcome> is "Full Approval."
- **(2) Conditional / Accelerated Approval.** Otherwise, if within <time period> (a) the FDA issues an approval for <drug> (and, where the Exchange has specified an indication, for an indication that encompasses the specified indication) that is granted under, or expressly subject to, the FDA's accelerated approval pathway or (b) the FDA grants any limited authorization for <drug>, the <outcome> is "Conditional / Accelerated Approval." This category captures FDA dispositions that permit some authorized use of <drug> on a conditional, accelerated, provisional, emergency, or otherwise limited basis short of a full standard marketing approval, including an accelerated approval and any limited authorization. For the avoidance of doubt, rules (1) and (2) are mutually

exclusive: a full standard (traditional) marketing approval is classified under rule (1), whereas an accelerated approval or a limited authorization is classified under rule (2), and never as both. A disposition counts under rule (1) or rule (2) regardless of any Risk Evaluation and Mitigation Strategy (REMS), boxed warning, or distribution restriction attached to it, and regardless of any subsequent withdrawal of that approval or authorization after it is granted.

- **(3) Denied (CRL Issued).** Otherwise, if neither rule (1) nor rule (2) governs and the FDA issues a Complete Response Letter for the application within <time period>, the <outcome> is "Denied (CRL Issued)." A subsequent withdrawal of the application following a CRL does not change this classification.
- **(4) Withdrawn by Sponsor.** Otherwise, if neither rule (1) nor rule (2) governs, no Complete Response Letter is issued within <time period>, and <drug manufacturer> effectuates a withdrawal of the application within <time period>, the <outcome> is "Withdrawn by Sponsor."
- **(5) No Decision.** Otherwise (none of rules (1) through (4) applies — within <time period> the FDA issues no approval, grants no limited authorization, and issues no Complete Response Letter, and the applicant effectuates no withdrawal; for example, where the FDA extends its review or the application remains pending as of the end of <time period>), the <outcome> is "No Decision."

Additional clarification(s):

- **Announcement governs; timing.** An FDA disposition is treated as occurring on the date the FDA issues the operative document (approval letter, CRL) or the date the applicant effectuates withdrawal, as documented by the Source Agency. A disposition documented only after Expiration is not accounted for and is treated, for resolution purposes, as not having occurred within <time period>.
- **Narrower-indication approvals.** Where the Exchange has specified an indication, an FDA approval limited to a population or indication narrower than the specified indication, such that it does not encompass the specified indication, does not constitute an approval under rule (1) or rule (2); the classification then proceeds under the remaining rules with respect to the specified indication. The Exchange will announce any determination that an approved indication is the substantive equivalent of the specified indication pursuant to Rule 7.1.
- **Advisory committees and interim communications.** Advisory Committee votes or recommendations, FDA information requests, refuse-to-file letters, and PDUFA-date extensions do not, in themselves, constitute an approval, a CRL, or a withdrawal, and do not resolve the Contract. Only the operative documents defined above govern.

The following are examples for illustration. In each scenario, the named <outcome> strike resolves Yes and every other listed <outcome> strike resolves No.

- The FDA issues a standard (traditional) approval letter for <drug> within <time period>, not designated as an accelerated approval. — "Full Approval."
- The FDA approves <drug> within <time period> and the approval letter designates it an accelerated approval based on a surrogate endpoint, with a required confirmatory trial. — "Conditional / Accelerated Approval."

- The FDA grants an Emergency Use Authorization for <drug> within <time period> and does not issue a full or accelerated marketing approval, a CRL, or a withdrawal within <time period>. — "Conditional / Accelerated Approval" (an EUA is a limited authorization under rule (2)).
- Within <time period> the FDA grants an Emergency Use Authorization for <drug>, and in a later <time period> issues a full standard marketing approval; for the iteration whose <time period> contains the EUA only, the <outcome> is "Conditional / Accelerated Approval," and for the iteration whose <time period> contains the full approval, the <outcome> is "Full Approval."
- The FDA grants a tentative approval of an ANDA for <drug> within <time period> (the application meets approval requirements but final approval is barred by an unexpired patent), with no final approval within <time period>. — "Conditional / Accelerated Approval."
- The FDA issues a standard approval with a REMS and a boxed warning within <time period>. — "Full Approval" (REMS and labeling restrictions do not change the pathway).
- The FDA issues a Complete Response Letter within <time period>, and the FDA grants no approval or limited authorization within <time period>. — "Denied (CRL Issued)."
- The FDA issues a CRL within <time period> (with no approval or limited authorization granted); the sponsor then withdraws the application within <time period>. — "Denied (CRL Issued)" (the CRL governs; a post-CRL withdrawal does not change the classification).
- Anticipating a negative decision, <drug manufacturer> withdraws the application two weeks before the PDUFA date, within <time period>, before any FDA final action and with no approval, limited authorization, or CRL within <time period>. — "Withdrawn by Sponsor."
- The FDA extends the PDUFA date by three months following a major amendment, and no approval, limited authorization, CRL, or withdrawal occurs within <time period>. — "No Decision."
- Within <time period>, the FDA receives a CRL response and resubmission and then issues an approval letter, all within <time period>. — "Full Approval" or "Conditional / Accelerated Approval" per the approval letter (rule (1) or rule (2) governs because an approval issued within <time period>).

Minimum Tick: The Minimum Tick size for the Contract shall be $0.01.

Position Accountability Level: The Position Accountability Level for the Contract shall be $25,000 per strike, per Member.

Last Trading Date: The Last Trading Date of the Contract will be the Expiration Date. The Last Trading Time will be the Expiration time.

Settlement Date: The Settlement Date of the Contract shall be no later than the day after the Expiration Date, unless the Market Outcome is under review pursuant to Rule 7.1.

Expiration Date: The latest Expiration Date of the Contract shall be one week after the final day of <time period>. If an event described in the Payout Criterion occurs, expiration will be moved to an earlier date and time in accordance with Rule 7.2.

Expiration time: The Expiration time of the Contract shall be 10:00 AM ET.

Settlement Value: The Settlement Value for this Contract is $1.00.

Expiration Value: The Expiration Value is the value of the Underlying as documented by the Source Agency on the Expiration Date at the Expiration time.

Contingencies: Before Settlement, Kalshi may, at its sole discretion, initiate the Market Outcome Review Process pursuant to Rule 7.1 of the Rulebook. If an Expiration Value cannot be determined on the Expiration Date, Kalshi has the right to determine payouts pursuant to Rule 7.1 in the Rulebook.

APPENDIX B – TRADING PROHIBITIONS

In addition to the general prohibition against trading on material nonpublic information, the Exchange will institute additional prohibitions for trading the contract. Persons under 18 years of age are not permitted to create Kalshi accounts. The following individuals will be prohibited from trading:

- Officers, directors, employees, contractors, and consultants of <drug manufacturer>, including its subsidiaries, affiliates, joint-venture partners, co-development partners, and licensees, who have access to non-public information regarding the regulatory status, review timeline, or anticipated FDA decision for <drug>.
- Officers, directors, employees, reviewers, and review staff of the FDA — including the relevant review division, the Office of New Drugs, and the Center for Drug Evaluation and Research or Center for Biologics Evaluation and Research — with access to non-public submissions, review documents, inspection findings, deficiency communications, or decisional materials relating to the application for <drug>.
- Members of any FDA advisory committee convened to evaluate <drug>, from the time of their appointment to such committee through resolution of the Contract.
- Principal investigators, sub-investigators, clinical research coordinators, and site staff for the clinical trials supporting the application for <drug>, to the extent they have access to non-public information bearing on the FDA decision or its timing.
- Employees, contractors, and consultants of contract research organizations (CROs), regulatory-affairs firms, central laboratories, biostatistical firms, and data-management vendors engaged by <drug manufacturer> in connection with the application for <drug>.
- Persons who have entered into confidentiality, consulting, or expert-network agreements with <drug manufacturer> or its agents that provide access to non-public information regarding the timing or content of the FDA decision for <drug>.
- Employees of investment banks, financial advisors, or other advisors engaged by <drug manufacturer> or its partners to advise on transactions, financing, or strategic decisions materially related to <drug>, to the extent such persons possess non-public information regarding the FDA decision or its timing.
- Immediate family members (spouses, domestic partners, parents, children, and siblings) and household members of any of the above.
- Any person who has obtained material non-public information regarding the timing, content, or outcome of the FDA decision for <drug> through any means, including inadvertent disclosure, misappropriation, or breach of a confidentiality obligation.