June 25, 2025

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 approve <drug> before <date>?" 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 approve <drug> before <date>?" contract (Contract). The Contract will initially be listed after close-of-business on **June 25, 2025**; 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:

- **<date>**
- **<drug>**
- **<drug manufacturer>**

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 approve <drug> before <date>?"
Rulebook: GENFDAAPPROVAL
Summary: FDA drug approval before specified date
Kalshi Contract Category: Health/Science
Kalshi Internal Category: Health
June 25, 2025

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 approve <drug> before <date>?" 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 B, C, and D.

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 5.12 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 3.6 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 25, 2025

Attachments:

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

APPENDIX A – CONTRACT TERMS AND CONDITIONS

Official Product Name: "Will the FDA approve <drug> before <date>?"
Rulebook: GENFDAAPPROVAL

GENFDAAPPROVAL

Scope: These rules shall apply to this contract.

Underlying: The Underlying for this Contract is the U.S. Food and Drug Administration's regulatory decision on <drug> after Issuance and before <date>. Revisions to the Underlying made after Expiration will not be accounted for in determining the Expiration Value.

Source Agency: The Source Agencies are the U.S. Food and Drug Administration, ClinicalTrials.gov, the Federal Register, <drug manufacturer>, The New York Times, the Associated Press, Bloomberg News, Reuters, Axios, Politico, Semafor, The Information, The Washington Post, The Wall Street Journal, ABC, CBS, CNN, Fox News, MSNBC, NBC, STAT News, FiercePharma, BioPharma Dive, Endpoints News, The Pink Sheet, and FDA News.

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 any pharmaceutical product, biologic, vaccine, or therapeutic that is either specified by the Exchange or possesses a specific property or characteristic specified by the Exchange. This includes any drug, regardless of its generic name, brand name, specific formulation, dosage, or delivery method, that demonstrates or is indicated for a specified property or therapeutic effect as determined by the Exchange. Multiple drugs may qualify under this definition if they possess the specified property. If multiple qualifying drugs exist, the Contract resolves to "Yes" upon FDA approval of any one drug that meets the property criteria. The Exchange will specify the exact property or characteristic that defines <drug> for each Contract iteration.

<date>: <date> refers to a calendar date specified by the Exchange. The Exchange may list iterations of the Contract corresponding to variations of <date>.

Payout Criterion: The Payout Criterion for the Contract encompasses the Expiration Values that the FDA has approved <drug> for marketing in the United States after Issuance and before <date>. An approval is defined as:

- For new drugs: FDA issuance of an approval letter for a New Drug Application (NDA) or Biologics License Application (BLA)
- For already-marketed drugs seeking new indications: FDA approval of a supplemental NDA (sNDA) or supplemental BLA (sBLA) for the specific indication referenced
- For generic drugs: FDA approval of an Abbreviated New Drug Application (ANDA)
- For biosimilars: FDA approval of a 351(k) application

The following constitute approvals that trigger the Payout Criterion:

- Standard approval (traditional approval based on clinical benefit)
- Accelerated approval (based on surrogate endpoints)
- Approval with Risk Evaluation and Mitigation Strategy (REMS)
- Approval with restricted distribution or indication limitations, except compassionate use/expanded access programs

The following do NOT constitute approvals:

- Complete Response Letters (CRLs) indicating the application cannot be approved in its current form
- Approvable letters that require additional actions before approval
- Tentative approvals pending patent or exclusivity expiration
- FDA requests for additional information or studies
- Extension of Prescription Drug User Fee Amendments dates
- Approval for compassionate use or expanded access programs only
- Emergency Use Authorization (EUA) without full approval
- Approval only for export or for use outside the United States

If the FDA issues a Complete Response Letter before <date>, the market will resolve to "No" unless the FDA subsequently approves the drug after addressing the CRL concerns and before <date>.

If the FDA convenes an Advisory Committee that votes against approval but the FDA approves <drug> anyway before <date>, the market will resolve to "Yes."

If <drug> receives accelerated approval that is later withdrawn before <date>, the market will resolve based on whether the initial accelerated approval occurred after Issuance (Yes) regardless of the subsequent withdrawal.

If the drug sponsor withdraws the application before FDA action and before <date>, the market will resolve to "No" immediately.

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 day prior to <date>. The Last Trading Time will be 11:59 PM ET.

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 <date>. 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 6.3(d) of the Rulebook. If an Expiration Value cannot be determined on the Expiration Date, Kalshi has the right to determine payouts pursuant to Rule 6.3(b) in the Rulebook.