

March 23, 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 <company> submit an <application> for <drug> <time period>?” 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 <company> submit an <application> for <drug> <time period>?” contract (Contract). The Contract will initially be listed after close-of-business on **March 24, 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:

- <date>
- <company>
- <application>
- <drug>
- <time period>

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 <company> submit an <application> for <drug> <time period>?”

Rulebook: NEWDRUGAPPLICATION

Summary: Company’s drug application submission by deadline

Kalshi Contract Category: Health/Science

Kalshi Internal Category: Health

March 23, 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 <company> submit an <application> for <drug> <time period>?” 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](mailto:ProductFilings@kalshi.com).



---

By: Xavier Sottile  
Title: Head of Markets  
Date: March 23, 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 <company> submit an <application> for <drug> <time period>?”**

**Rulebook: NEWDRUGAPPLICATION**

## NEWDRUGAPPLICATION

**Scope:** These rules shall apply to this contract.

**Underlying:** The Underlying for this Contract is the regulatory submission status of <application> by <company> for <drug> during <time period>. Revisions to the Underlying made after Expiration will not be accounted for in determining the Expiration Value.

**Source Agency:** The Source Agencies are, in hierarchical order, the U.S. Food and Drug Administration (FDA) and its official databases, portals, and public communications (including the FDA's Drugs@FDA database, official FDA press releases, FDA approval letters, and the FDA's official website), the European Medicines Agency (EMA) and its official public registry, any other applicable national or supranational regulatory authority explicitly identified by the Exchange at the time of listing, the official investor relations disclosures, press releases, and regulatory filings (including SEC Forms 10-K, 10-Q, and 8-K, or equivalent filings with applicable regulatory or exchange bodies) of <company>, Bloomberg, Reuters, The Wall Street Journal, Financial Times, STAT News, BioPharma Dive, The Associated Press, and S&P Global Market Intelligence.

**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.

**<company>:** <company> refers to a specific pharmaceutical, biotechnology, or life sciences company or corporate entity as specified by the Exchange, identified by its legal name, ticker symbol, or widely recognized trade or brand name. <company> may refer to a singular entity, a consolidated parent entity inclusive of subsidiaries and affiliated entities, or a named subsidiary or division thereof as explicitly specified by the Exchange. For purposes of this Contract, a submission made by a wholly owned subsidiary, a designated agent, or a licensing partner acting on behalf of <company> in an official regulatory capacity shall be treated as a submission by <company>, provided that <company> is identified as the applicant of record or sponsor of record in the relevant submission. If <company> undergoes a name change, ticker change, merger, acquisition, spin-off, or other corporate restructuring during <time period>, the Exchange will determine the appropriate successor entity and announce this to Members. <company> may also refer to multiple companies (using AND or OR logic as specified by the Exchange), a company identified by distinguishing characteristics, or "Any" or "None."

**<application>:** <application> refers to a specific type of regulatory submission as specified by the Exchange. This may include, but is not limited to:

- A New Drug Application (NDA) submitted to the FDA under 21 C.F.R. Part 314, including Standard NDAs and Priority Review NDAs;
- A Biologics License Application (BLA) submitted to the FDA under 21 C.F.R. Part 601;
- An Abbreviated New Drug Application (ANDA) submitted to the FDA under 21 C.F.R. Part 314, Subpart C;
- A supplemental NDA (sNDA) or supplemental BLA (sBLA), whether seeking approval for a new indication, new dosage form, new route of administration, new dosing regimen, labeling change, or manufacturing change;
- A Marketing Authorization Application (MAA) submitted to the EMA or a comparable submission to any other regulatory authority explicitly identified by the Exchange; or
- Any other formal regulatory submission type as explicitly defined by the Exchange at the time of listing.

<application> may refer to a singular application type, multiple application types (using AND or OR logic as specified by the Exchange), or an application type identified by distinguishing characteristics. Unless otherwise specified by the Exchange, <application> shall refer to an original or initial submission and not to a resubmission, amendment, or response to a Complete Response Letter (CRL) or equivalent regulatory request, except where such resubmission or response is explicitly designated as <application> by the Exchange at the time of listing.

**<drug>:** <drug> refers to a specific pharmaceutical compound, biologic, therapeutic agent, combination product, or drug candidate as specified by the Exchange. <drug> may be identified by its International Nonproprietary Name (INN), United States Adopted Name (USAN), brand name, development code name, or chemical name, or name used in common parlance, as specified by the Exchange. If <drug> is identified by a development code name and subsequently receives an INN, USAN, or brand name, the identity of <drug> shall remain consistent throughout the Contract and such naming changes shall not create a new drug for purposes of this Contract. <drug> may also be defined by a specific indication, dosage form, strength, route of administration, or patient population as specified by the Exchange, in which case the <application> must correspond to those specific characteristics to satisfy the Payout Criterion. <drug> may refer to a singular compound, multiple compounds, or a compound identified by distinguishing characteristics, and may also take the values "Any" or "None." If <drug> undergoes a material reformulation, combination with another agent, or change in mechanism of action such that it is no longer substantially equivalent to the compound originally identified, the Exchange will determine whether the reformulated compound continues to constitute <drug> for purposes of this Contract and will announce this determination to Members.

**<time period>:** <time period> refers to a specific range of time in which the submission of <application> must occur in order to satisfy the Payout Criterion, as specified by the Exchange. This may be defined by exact dates (e.g., "between January 1, 2026, and December 31, 2026"), relative markers (e.g., "before July 1, 2027"), broader intervals (e.g., "Q1–Q2 2027," "calendar

year 2026"), or by reference to a specific regulatory or clinical milestone event as defined by the Exchange. "Between" is inclusive of both endpoints, while "before" and "after" exclude the specified date unless stated otherwise. <time period> may also refer to "Any" or "None", to multiple periods (even if non-consecutive), or to a singular discrete date or time.

**Payout Criterion:** The Payout Criterion for the Contract encompasses the Expiration Values that <company> submits <application> for <drug> during <time period> and before the Expiration Date, as documented by the Source Agency.

**Additional clarification(s):**

- "Submits" means that <company>, or a designated agent, subsidiary, or licensing partner acting on <company>'s behalf in an official regulatory capacity, has formally tendered <application> to the applicable regulatory authority <time period>, such that the regulatory authority has received and logged the submission as a pending filing. Submission is deemed to have occurred on the date the regulatory authority officially receives the application, not on the date of any subsequent acceptance, refusal to file, approval, or other regulatory action taken with respect to that submission.
- A submission that is subsequently refused to file (RTF) by the applicable regulatory authority, or that receives a refusal to file decision, a refuse to receive decision, or any equivalent administrative rejection prior to formal acceptance, shall nonetheless count as a submission for purposes of this Contract, provided that the regulatory authority confirmed receipt of the application prior to issuing such a determination.
- A submission that is withdrawn by <company> after having been received by the applicable regulatory authority shall count as a submission for purposes of this Contract, provided that withdrawal occurs after the regulatory authority confirmed receipt. A withdrawal prior to confirmed receipt shall not count as a submission.
- A rolling submission, in which <company> submits completed sections of <application> to the applicable regulatory authority on a rolling basis prior to the complete submission, shall be deemed to constitute a submission for purposes of this Contract on the date the regulatory authority confirms receipt of the complete submission package, unless the Exchange explicitly specifies otherwise at the time of listing.
- A Pre-New Drug Application (pre-NDA) meeting, a Type A, B, or C meeting with the FDA, the submission of an Investigational New Drug application (IND), a Breakthrough Therapy Designation request, a Fast Track Designation request, a Rare Pediatric Disease Designation request, an Orphan Drug Designation request, or any other pre-submission regulatory interaction or designation request shall not constitute a submission of <application> for purposes of this Contract.
- A resubmission of <application> following a Complete Response Letter (CRL), a withdrawal and refiling, or an amendment to a pending application shall not constitute a new submission of <application> for purposes of this Contract unless such resubmission

or amendment is explicitly designated as <application> by the Exchange at the time of listing. If the Contract is specifically listed to track a resubmission, the same rules governing original submissions shall apply mutatis mutandis.

- If <application> specifies a particular indication, dosage form, strength, route of administration, or patient population, a submission that does not correspond to those specified characteristics shall not satisfy the Payout Criterion, even if <company> submits a different application for <drug> during <time period>.
- If <company> submits <application> for <drug> jointly with one or more co-sponsors or co-applicants, and <company> is identified as a co-applicant or co-sponsor of record, such a joint submission shall satisfy the Payout Criterion.
- If <company> out-licenses or transfers the rights to <drug> to a third party prior to submission, and the third party submits <application> in its own name as the applicant of record without <company> being identified as a co-applicant, co-sponsor, or agent of record, such a submission shall not satisfy the Payout Criterion unless the Exchange determines otherwise and announces such determination to Members.
- If <company> undergoes a merger, acquisition, spin-off, going-private transaction, bankruptcy filing, or dissolution prior to or during <time period> such that the identity of the appropriate applicant entity cannot be determined with reasonable certainty, the Contract will be subject to the Contingencies provisions set forth below.
- If the applicable regulatory authority suspends, places a clinical hold on, or otherwise administratively prevents <company> from submitting <application> for <drug> during <time period> due to a regulatory, legal, or safety action not caused by <company>, the Contract will be subject to the Contingencies provisions set forth below.
- If the applicable regulatory authority ceases to exist, is restructured, or is replaced by a successor authority during <time period>, and <company> submits <application> to the recognized successor authority, such a submission shall satisfy the Payout Criterion at the discretion of the Exchange, which will announce this determination to Members.
- If <company> publicly announces an intention to submit <application> for <drug> during <time period> but does not complete the submission prior to the Expiration Date, such an announcement shall not satisfy the Payout Criterion. The Payout Criterion requires confirmed receipt of the submission by the applicable regulatory authority, not merely the announcement of intent to submit.
- If <company> submits <application> for <drug> to a regulatory authority other than the one explicitly identified in the Contract or implied by the applicable regulatory framework (e.g., submitting to the EMA when the Contract contemplates an FDA submission), such a submission shall not satisfy the Payout Criterion unless the Exchange determines otherwise and announces such determination to Members.
- For contracts in which <application> refers to a supplemental application (e.g., sNDA or sBLA), the supplemental submission must be for the specific new indication, dosage form, labeling change, or other modification explicitly identified by the Exchange in

order to satisfy the Payout Criterion. A supplemental submission for a different modification shall not satisfy the Payout Criterion even if it concerns <drug>.

**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, and contractors of <company>, including but not limited to the Chief Executive Officer, Chief Scientific Officer, Chief Medical Officer, Chief Regulatory Officer, General Counsel, and any member of <company>'s regulatory affairs, clinical development, medical affairs, legal, investor relations, or corporate strategy departments with access to non-public information regarding the timing, status, or content of <application> for <drug>.
- Members of <company>'s board of directors, including independent directors and any persons serving on <company>'s science, development, or regulatory committees.
- Employees, consultants, and contractors of any contract research organization (CRO), contract manufacturing organization (CMO), or regulatory consulting firm retained by <company> in connection with the development, manufacturing, or regulatory submission of <drug>, who have access to non-public information regarding the timing or status of <application>.
- Employees and partners of <company>'s external legal counsel or regulatory counsel engaged in connection with the preparation, review, or submission of <application> for <drug>.
- Employees and officials of the applicable regulatory authority (including the FDA, EMA, or any other regulatory body identified by the Exchange) who have access to non-public information regarding the receipt, review, acceptance, or status of <application> for <drug>, including but not limited to review division staff, Office of New Drugs personnel, advisory committee members assigned to review <drug>, and any equivalent officials at the EMA or other applicable authority.
- Employees and partners of <company>'s external auditor or independent registered public accounting firm who have access to non-public information regarding <company>'s regulatory submission timelines or material corporate events relating to <drug>.
- Employees, officers, and directors of any co-development partner, licensee, licensor, co-sponsor, or co-applicant of <company> with respect to <drug>, who have access to non-public information regarding the timing or status of <application>.
- Investors, board members, and venture capital or private equity professionals with board seats, board observation rights, advisory roles, or information rights at <company> or at any co-development partner, to the extent such persons have access to non-public regulatory submission timelines, clinical data readouts, or strategic decisions relating to <drug> or <application>.

- Immediate family members (including parents, siblings, spouses, domestic partners, and children) and household members of any of the above persons.