Official Product Name: “Will the FDA approve <drug> before <date>?”

Rulebook: GENFDAAPPROVAL

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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[a]. 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.