access for U.S. market participants to non-U.S. markets in realization of the global economy and international business.[3] The main substantive amendment in today's Proposed FBOT Amendments is to Regulation 48.4, which currently permits futures commission merchants (FCMs), commodity pool operators (CPOs), and commodity trading advisors (CTAs) to enter orders on behalf of customers or commodity pools via direct access on a registered FBOT.[4]

As explained in the Proposal, the Commission is proposing to permit introducing brokers (IBs)[5] to submit customer orders via direct access to FBOTs by adding IBs to the list of permissible intermediaries in Regulation 48.4. Doing so would permit IBs to act as executing brokers for U.S. customers that in turn use another intermediary, like an FCM,[6] for clearing and carrying the customer accounts, similar to the way IBs currently perform this service on CFTC-registered designated contract markets (DCMs). Among other benefits, U.S. market participants interested in trading foreign futures could have more choices in brokers and broker arrangements. The Proposed FBOT Amendments will also ensure that customer protections are in place, similar to the current FBOT requirements for FCMs, CPOs, and CTAs.

As sponsor of the CFTC's Global Markets Advisory Committee (GMAC),[7] I have devoted a significant part of my Commissionership to supporting solutions that will enhance the resiliency and efficiency of global markets.[8] The Proposal is policy that mitigates market fragmentation and the associated impact on liquidity, and promotes the overall competitiveness of our derivatives markets. I am pleased to support the Proposed FBOT Amendments, and I look forward to the public comments.

[FR Doc. 2024–04117 Filed 2–29–24; 8:45 am]

BILLING CODE 6351–01–P

[3] While FBOTs initially had operated pursuant to no-action relief, in 2011, following the Dodd-Frank Wall Street and Consumer Protection Act of 2010, the Commission began registering FBOTs. *See* Registration of Foreign Boards of Trade, Final Rule, 76 FR 80674 (Dec. 23, 2011), *https://www.federalregister.gov/documents/2011/12/23/2011-31637/registration-of-foreign-boards-of-trade.*

[4] *See* 17 CFR 48.4.

[5] The Commission generally defines an IB as an individual or organization that solicits or accepts orders to buy or sell futures contracts, commodity options, retail off-exchange forex or commodity contracts, or swaps, but does not accept money or other assets from customers to support these orders. *See* CEA section 1a(31); 17 CFR 1.3(mm). The Commission registers IBs under CEA section 4d(g) and Regulation 3.4(a). *See* 7 U.S.C. 6d(g) and 17 CFR 3.4(a).

[6] U.S. customers could also use a firm exempted by the Commission pursuant to Regulation 30.10. The CFTC's part 30 regulations govern the offer and sale of foreign futures and options contracts to U.S. customers. Regulation 30.4 requires that in order to accept any money, securities or property (or extend credit in lieu thereof) to margin, guarantee or secure transactions conducted by U.S. persons on an FBOT, a person must be registered as an FCM. See 17 CFR 30.4(a). The Commission may grant and has granted exemptions to this requirement to register as an FCM based on petitions filed pursuant to 17 CFR 30.10. A Regulation 30.10 exemptive order permits firms subject to regulation by a foreign regulator to conduct business from locations outside of the U.S. for U.S. persons on FBOTs without registering as FCMs, based upon the firm's substituted compliance with a foreign regulatory structure found comparable to that administered by the Commission under the CEA.

[7] Commissioner Pham Announces New Members and Leadership of the CFTC's Global Markets Advisory Committee and Subcommittees (June 30, 2023), *https://www.cftc.gov/PressRoom/PressReleases/8740-23.*

[8] Opening Statement of Commissioner Caroline D. Pham before the Global Markets Advisory Committee (Feb. 13, 2023), *https://www.cftc.gov/PressRoom/SpeechesTestimony/phamstatement021323.* Most recently, the GMAC made eight recommendations to the CFTC that promote access to markets and competition while safeguarding financial stability. CFTC Global Markets Advisory Committee Advances Key Recommendations (Feb. 8, 2024), *https://www.cftc.gov/PressRoom/PressReleases/8860-24.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 50

[Docket No. FDA–2022–D–2997]

Key Information and Facilitating Understanding in Informed Consent; Draft Guidance for Sponsors, Investigators, and Institutional Review Boards; Availability

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, and the Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Office for Human Research Protections, Office of the Assistant Secretary for Health (OHRP), and the Food and Drug Administration (FDA) are announcing the availability of a draft guidance entitled ''Key Information and Facilitating Understanding in Informed Consent.'' This draft guidance provides recommendations related to two provisions of the revised Federal Policy for the Protection of Human Subjects (the revised Common Rule) by the U.S. Department of Health and Human Services (HHS) and identical provisions in FDA's proposed rule ''Protection of Human Subjects and Institutional Review Boards.'' FDA's proposed rule, if finalized, would harmonize certain sections of FDA's regulations on human subject protections and institutional review boards (IRBs), to the extent practicable and consistent with other statutory provisions, with the revised Common Rule, in accordance with the 21st Century Cures Act (Cures Act). The guidance addresses the provisions of the revised Common Rule that require informed consent to begin with key information about the research and to present information in a way that facilitates understanding and identical provisions in FDA's proposed rule.

DATES: Submit either electronic or written comments on the draft guidance by April 30, 2024 to ensure that FDA and OHRP consider your comment on this draft guidance before the agencies begin work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–2997 for ''Key Information and Facilitating Understanding in Informed

Consent.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002, 800–835–4709 or 240–402–8010; the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002, *CDRH-Guidance@fda.hhs.gov;* the Office of Clinical Policy, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993, 301–796–8340, or the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Pkwy., Suite 200, Rockville, MD 20852, 240–453–6900 or 866–447–4777; *ohrp@hhs.gov.* Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Alyson Karesh, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6356, Silver Spring, MD 20993–0002, 301–796–3826; James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; Soma Kalb, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3516, Silver Spring, MD 20993, 301–796–5490; the Office of Clinical Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993, 301–796–8340; or the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Pkwy., Suite 200, Rockville, MD 20852, 240–453–6900 or 866–447–4777.

SUPPLEMENTARY INFORMATION:

I. Background

FDA and OHRP are announcing the availability of a draft guidance entitled ''Key Information and Facilitating Understanding in Informed Consent.'' This draft guidance provides recommendations related to two provisions of the revised Common Rule and identical provisions in FDA's proposed rule ''Protection of Human Subjects and Institutional Review Boards'' (87 FR 58733, September 28, 2022). The FDA's proposed rule, if finalized, would harmonize certain sections of FDA's regulations on human subject protection and IRBs, to the extent practicable and consistent with other statutory provisions, with the revised Common Rule (codified by the Department of Health and Human Services at 45 CFR part 46, subpart A), in accordance with the Cures Act (Pub. L. 114–255, section 3023). The guidance addresses the provisions of the revised Common Rule that require informed consent to begin with key information about the research and to present information in a way that facilitates understanding and identical provisions in FDA's proposed rule.

In this draft guidance, FDA and OHRP provide recommendations for developing a key information section for clinical trials or studies, including strategies to make consent information as a whole more understandable for prospective research participants. We also provide a sample approach to the key information section that is based, in part, on research regarding patient understanding of information found in labeling for prescription drugs. By using simple phrases and plain language principles, as well as formatting and organizational tools, researchers found that presenting information in a discrete bubble format with topics organized or grouped together can facilitate consumer understanding.[1] In the appendix of the draft guidance, we provide an example of a key information section using the bubble format. We encourage interested parties, with input from IRBs, to develop innovative ways to provide key information that will help prospective subjects better understand the reasons why one might or might not want to participate in research.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on ''Key Information and Facilitating Understanding in Informed Consent.'' It does not establish any rights for any person and is not binding on FDA, OHRP, or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.[2]

[1] Boudewyns, V., A.C. O'Donoghue, B. Kelly, et al. (2015), ''Influence of Patient Medication Information Format on Comprehension and Application of Medication Information: A Randomized, Controlled Experiment,'' *Patient Education and Counseling,* vol. 98(12), pp. 1592–1599, *https://doi.org/10.1016/j.pec.2015.07.003.*

[2] The Office of the Federal Register has published this document under the category ''Rules and Regulations'' pursuant to its interpretation of 1 CFR 5.9(b). We note that the categorization as such for purposes of publication in the **Federal Register** does not affect the content or intent of the document. See 1 CFR 5.1(c).

II. Paperwork Reduction Act of 1995

This draft guidance refers to proposed collections of information described in FDA's September 28, 2022, proposed rule on ''Protection of Human Subjects and Institutional Review Boards'' (87 FR 58733), which this draft guidance is intended to interpret, and with previously approved collections of information described in the revised Federal Policy for the Protection of Human Subjects (the revised Common Rule). The proposed collections of information in the proposed rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). As required by the PRA, FDA has published an analysis of the information collection provisions of the proposed rule (87 FR 58733 at 58744) and they have been approved under OMB control number 0910–0130. The collections of information in 45 CFR 46 and the final rule entitled, ''Federal Policy for the Protection of Human Subjects'' (Common Rule) have been approved under OMB control number 0990–0260.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, https://www.fda.gov/about-fda/office-clinical-policy-and-programs/office-clinical-policy, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, http://www.hhs.gov/ohrp/newsroom/rfc/index.html,* or *https://www.regulations.gov.*

Dated: February 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04377 Filed 2–29–24; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2023–0626; FRL–11614–03–R9]

Air Plan Disapproval; California; Los Angeles-South Coast Air Basin; 1997 8-Hour Ozone; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Environmental Protection Agency (EPA) is extending the comment period for a proposed rule published February 2, 2024. The current comment period for the proposed rule was set to end on March 4, 2024. In response to requests from several commenters, the EPA is extending the comment period for the proposed action to April 3, 2024.

DATES: The comment period for the proposed rule published on February 2, 2024, at 89 FR 7320 is extended. Comments must be received on or before April 3, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2023–0626 at *https://www.regulations.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Ginger Vagenas, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3964 or by email at *vagenas.ginger@epa.gov.*

SUPPLEMENTARY INFORMATION: On February 2, 2024, the EPA published a proposal to disapprove a state implementation plan revision submitted by the State of California to meet Clean Air Act (CAA) requirements for the 1997 8-hour ozone national ambient air quality standards (NAAQS) in the Los Angeles-South Coast Air Basin, California ozone nonattainment area. This submission, titled ''Final Contingency Measure Plan—Planning for Attainment of the 1997 80 ppb 8-hour Ozone Standard in the South Coast Air Basin,'' addresses the CAA requirements for the submission of contingency measures that will be implemented if emissions reductions from anticipated technologies associated with the area's 1997 ozone NAAQS attainment demonstration are not achieved. For more detailed information about this matter, please refer to the February 2, 2024 **Federal Register** document.

The notice of proposed rulemaking initially provided for comments to be submitted to the EPA on or before March 4, 2024 (a 30-day public comment period). The EPA received several comments requesting an extension of the comment period. To ensure the public has sufficient time to evaluate the proposal and develop comments, the EPA is extending the comment period until April 3, 2024.

Dated: February 23, 2024.

Matthew Lakin,

Acting Director, Air and Radiation Division, Region IX.

[FR Doc. 2024–04287 Filed 2–29–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2023–0617; FRL–11781–01–R3]

Air Plan Approval; Delaware; Amendments to Delaware's Requirements for Public Notice of Certain Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a