acquiring control of voting shares of Montecito Bancorp; and thereby indirectly acquiring control of voting shares of Montecito Bank & Trust, both of Santa Barbara, California.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–17073 Filed 8–1–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1532]

Agency Information Collection Activities; Proposed Collection; Comment Request: Risk/Safety Considerations and Motivations for Purchase and Use of Kratom and Psychedelics Alone and in Combination With Other Substances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed study entitled ''Risk/Safety Considerations and Motivations for Purchase and Use of Kratom and Psychedelics Alone and in Combination With Other Substances.''

DATES: Either electronic or written comments on the collection of information must be submitted by October 1, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 1, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2024–N–1532 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Risk/Safety Considerations and Motivations for Purchase and Use of Kratom and Psychedelics Alone and in Combination With Other Substances.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 in 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.'' The Agency 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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733.

For copies of the questionnaire: Please contact the CDER Controlled Substances Program (CDER/CSP) at *cdercsp@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information

before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Risk/Safety Considerations and Motivations for Purchase and Use of Kratom and Psychedelics Alone and in Combination With Other Substances

OMB Control Number 0910–NEW

This information collection supports scientific research, as authorized by section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)), and section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)). Emerging data on kratom and psychedelics suggest increasing use of these substances in certain populations, and is accompanied by reports noting risk and safety concerns with their use. Understanding the social, behavioral, and environmental contexts and motivations for use is included in our need to protect the public's health, through data-informed strategic initiatives.

This study seeks to capture information on how consumers make decisions about how, where, and why they buy these substances; what, if any risk/safety considerations and tradeoffs they take into account in the decision-making process; and the behavioral considerations in assessing the quality of the product and perceived harm to self.

This study will collect data that will enable the Agency, through the market research vendor (Brightfield Group) awarded this contract, to collect and analyze data on supply and demand characteristics; perceived product quality, pricing, and product labeling; and the consumer's perceived health outcome expectations for purchase and use of kratom and psychedelics, and concurrent use of both and other drug products.

The key study objectives include:

- Understand the temporal relationships and correlate of purchase decisions and behaviors among consumers' segments.
- Understand how marketing strategies nudge purchase and affect use demand.
- Develop predictive insights on potential future use (behavior) patterns based on analysis of the quantitative data.
- Identify other products often purchased and used along with these two substances.

As part of its key priorities in preventing access to substances with potential risk/safety concerns or that could be abused or misused, the Center for Drug Evaluation and Research/Controlled Substances Program/Controlled Substances Initiative (CDER/CSP/CSI), proactively works to identify: (1) emerging new substances that may pose potential public health risk; and (2) unmet needs regarding these emerging substances (including scientific knowledge gaps on use and risk/safety patterns among U.S. populations). These efforts support other scientific initiatives by CDER to meet the Agency's public health mandate to develop public health strategies, as appropriate, in response to risk to the health of populations.

The program achieves these objectives by actively: (1) monitoring the policy landscape for shifts in policies that may have implications on substance or drug use and access in U.S. populations, (2) convening stakeholders for a strategic and timely response, and (3) identifying and leading special research projects, including funding exploratory studies to address knowledge gaps and through other strategic initiatives. These exploratory research projects include behavioral and social science research studies allowing CDER to capture data on real-world experiences with use, behavioral and environmental (including economic or supply and demand factors) motivations or reinforcements for use, or that influence purchase and use. Exploratory research projects, such as the current study on kratom and psychedelics can identify new or expanded areas for additional scientific investigations. Similarly, exploratory social and behavioral research studies improve CDER's ability to quantify motivations for use, characterize patterns of use and access, identify individual-perceived risks and health outcome expectations, and individual risk-aversion behaviors when making a decision to buy and use these substances, better enabling the Agency to anticipate and predict future risks among U.S. populations. Notably, the Agency's proactive and preventive efforts, in combination with other scientific investigations options, can support the consideration of, or the development of, policy guardrails to prevent abuse and misuse.

This exploratory study is intended as a strategic response to understand and characterize emergent risk/safety and perceived benefits reportedly linked to kratom and psychedelics. CDER/CSP/CSI behavioral and social science exploratory research studies do not change the FDA's practice of relying on randomized controlled trials (RCTs) in regulatory decision-making, nor do they seek to be the only source of scientific information that inform policies. Strategic studies recognize the dynamic environment and systems in which drugs are used, misused, or lead to addiction. This is especially the case with unapproved, unregulated substances like kratom and controlled substances like psychedelics, which remain unapproved by FDA for the treatment of any medical condition. These types of studies advance the Agency's understanding of the real-world uses of drugs and unapproved and unregulated substances through exploration of the multidimensional factors (including behavioral and social motivations for use) that contribute to abuse and misuse.

Strategic exploratory research, such as this one, are also consistent with FDA's Overdose Prevention Framework of: (1) encouraging harm reduction through innovation and education; and (2) protecting the public from unapproved, diverted, or counterfeit drugs presenting overdose risk. Kratom is one of the substances that make up the opioid ecosystem, suggesting that it can potentially present the risks of abuse, addiction, and misuse. It is noteworthy that FDA has not approved any prescription or over-the-counter drug products containing kratom or its two main chemical components, mitragynine and 7-hydroxymitragynine (7–OH-mitragynine). Hence, while the Agency actively encourages interested researchers to study kratom to address the knowledge gap about its full risk/safety effects when ingested by humans by conducting rigorous randomized clinical studies, currently, there are no FDA approved drug products containing kratom or its two main chemical components legally marketed in the United States.

Notably, kratom's unapproved status does not appear to have diminished its

growing popularity, with people using kratom to reportedly ''treat'' certain health conditions. Its chemical affinity with opioid and use among patients with opioids use disorder as a ''treatment'' is of public health concern for the Agency. An estimated 1.7 million Americans 14 years and older reportedly used the substance in 2021 according to the Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health data. Further, if the thousands of comments posted by the public in response to the Agency's publication of a **Federal Register** notice on August 16, 2021, entitled ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 4F–MDMB–BICA (4F–MDMB–BUTICA); Brorphine; Metonitazene; Eutylone (bk-EBDB); BMDP (3,4-Methylenedioxy-N-benzylcathinone); Kratom (mitragynine, 7-hydroxymitragynine); Phenibut; Reopening Comment Period'' (*https://www.federalregister.gov/documents/2021/08/16/2021-17498/international-drug-scheduling-convention-on-psychotropic-substances-single-convention-on-narcotic*), is an indication of its popularity, the use of this substance, that has yet to be tested and determined safe for use in human population by the Agency, is a significant concern. Moreover, unapproved drug products are one of the most challenging areas for the Agency, including concerns with the quality of kratom products supplies that enter the country illegally and warning consumers of the risks from adulterated products. This challenge is in part due to the complex and fragmented supply chain networks that includes distributors, wholesalers, retailers, and user communities.

Psychedelics, although a Schedule 1 controlled substance under the Controlled Substances Act administered by the Drug Enforcement Agency (DEA), have recently seen a rapid resurgence with the growing interest in its use as a potential treatment for some mental health disorders. Further, the increasing social acceptance of psychedelics use among certain communities in the United States may also present public health risks. Although a Schedule 1 substance, there is no FDA-approved psychedelic drug, which does not appear to have diminished the growing interest in their use. The rapid pace of interest in psychedelics is evidenced by the number of research investigations and investigational new drug applications from certain groups. Psychedelics such as LSD, MDMA, and psilocybin are especially of interest. In the backdrop of shifting State policies to either decriminalize or legalize psychedelics, suggests a potential future in which these drugs are abused or people who use them are abused because of their vulnerable state of consciousness while under the influence of the drug.

Presently, there is little to no study on the co-occurrence of use of kratom and psychedelics. Further, our review of public databases of peer reviewed journals did not reveal any previous studies using behavioral economics and health outcome expectations theoretical framework to study the purchase and use of these two substances in U.S. populations. Consequently, we anticipate this study filling a key knowledge gap in our understanding of the behavioral and social drivers for purchase and use, with the potential for identifying areas for further scientific investigation.

The proposed research will use a mixed-methods design, involving in-depth interviews and survey of kratom and psychedelics consumers and a survey of non-users of these products as a comparison group. Our methodological approach will involve non-probabilistic samples. The design recognizes that non-probabilistic sampling approach has its limitations for generalizability due to inherent sampling bias. However, we feel confident that this limitation will be controlled and minimized through the analysis plan (economic modeling) proposed for this study. The proposed vendor for this sole source contract is a market research firm, Brightfield Group, that owns proprietary rights to a large database of over 5,000 comparable consumers of drug products and dietary supplements. In-depth (N = 36) interview participants will be recruited from this database. In-depth interview respondents will receive a $75 gift card for their time as a gift for the 60 minutes estimated for each person to complete the interview. In-depth interviews will be conducted online through video recording.

Survey respondents (N = 400 for group 1; *i.e.,* users of kratom and psychedelics) and N = 400 as a comparison group of non-kratom and psychedelics products (group 2). Both groups will be recruited and screened by a survey panel company, EMI Research Solutions (*https://emi-rs.com/*), sub-contracted by the vendor to conduct this online survey. EMI plans to use double-opt-in, market research panels to identify and survey participants. They will also submit two back-up sources for compliance in the instance that changing incidence rate or other unforeseen fielding difficulties necessitate utilizing additional resources. The company will pass a respondent-level panel-specific variable through the survey link so that it is contained in the study team's final survey data. Survey respondents will receive a cash incentive of no more than $4.50 based on the estimated 15 minutes to complete the online questionnaire. Incentive amount will be transparently disclosed to survey respondents prior to participation. This will be done via the recruitment outreach email invitation clearly displayed on the self-service portal. Interview respondents and the survey groups (*i.e.,* group 1 and group 2) will be screened for inclusion through a set of screening questions that ensures respondents meet inclusion criteria, such as recent use (within the last 6 months) of either drug. Efforts will also be made to include a diverse group of respondents based on age, geographic setting, intention to use the substance in the immediate future, and residency in the Unites States.

Description of Respondents:

In-depth interview respondents: The hour-long in-depth interview respondents will include a total of 36 consumers recruited from the vendor's proprietary market research database—*https://www.Evergi.com.* The platform includes data from consumers who have previously purchased and reported using drug products such as kratom or psychedelics in the past and have previously expressed interest in being contacted to participate in research studies.

Survey respondents: A combined of 400 kratom and psychedelics users (group 1) will be recruited for the study, as well as a comparison group (group 2) of 400 people who report that they have never used either kratom or psychedelics in the past. The inclusion criteria for participation in the survey will include:

- Age 18 years and older
- Have used kratom, psilocybin, MDMA, or LSD in the past 6 months. (The vendor plans to recruit 9 users of each substance.)
- Have used the substance at least two times in their life and say they will use it in the future.
- Live in the Unites States.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
Survey Group #1 (Target Group) (Consumers of Kratom or Psychedelics)					
In-depth interview	36	1	36	1	36
Questionnaire completion	400	1	400	0.17 (10 minutes)	68
Survey Group #2 (Comparison Group)					
Questionnaire completion (non-use of substances)	400	1	400	0.08 (5 minutes)	32
Total					136

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

Dated: July 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17102 Filed 8–1–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1527]

M12 Drug Interaction Studies; M12 Drug Interaction Studies: Questions and Answers; International Council for Harmonisation; Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the final guidance for industry entitled ''M12 Drug Interaction Studies'' and the supplemental document entitled ''M12 Drug Interaction Studies: Questions and Answers.'' The guidance and supplemental questions and answers document were prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The guidance provides general recommendations on evaluating the enzyme and transporter-mediated pharmacokinetic drug-drug interaction potential for investigational drugs. The supplemental questions and answers document provides clarity to some concepts related to evaluation of drug interactions covered in the guidance. The guidance is intended to harmonize the regional recommendations for designing, conducting, and interpreting in vitro and clinical evaluations of drug-drug interactions while developing investigational drugs. The guidance replaces the draft guidance ''M12 Drug Interaction Studies'' issued on August 29, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on August 2, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–1527 for ''M12 Drug Interaction Studies'' and ''M12 Drug Interaction Studies: Questions and Answers.'' 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.'' The Agency 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