POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING/STUDY DESIGN (PICOTS)—Continued

PICOTS	Inclusion	Exclusion
	KQs 4–6. Combined psychosocial and pharmacologic interventions included for KQs 1–3.	
Comparators	—Other included psychosocial and/or pharmacologic interventions —Inactive treatment, including waitlist control, no treatment and placebo.	No comparison group, excluded interventions.
Outcomes	KQs 1–4, 6. Behavioral outcomes: —Aggressive behavior. —Temper outbursts (not considered age-appropriate). —Violent behavior. —Delinquent behavior. —Fighting, property destruction, and rule violations. —Compliance with parents, teachers, and institutional rules. —Affective or mood elements of DBD. —Treatment satisfaction. —Other patient-centered outcomes. KQs 1–4, 6. Functional outcomes: —Family functioning/cohesion. —School performance/attendance. —Interpersonal/social function and competence/need for special accommodations. —Interactions with legal/juvenile justice systems. —Out of home placement. —Health care system utilization. —Substance abuse. —Parenting stress. —Logistical family outcomes (days of work lost, etc.). —Health-related quality of life (e.g., mental health, physical health). —Other patient-centered outcomes. KQ 5. Adverse effects/harms: —Metabolic effects: weight gain, hyperglycemia and diabetes, hyperlipidemia. —Extrapyramidal effects: parkinsonism, acute dystonia, akathisia, tardive dyskinesia. —Cardiac adverse effects: prolonged QT/arrhythmias, hypotension, cardiomyopathy. —Prolactin-related effects. —Neutropenia as a potential adverse effect of atypical antipsychotics. —Allergic reaction. —Sleep disruption, fatigue. —Sudden death. —Suicide. —Over-medication or inappropriate medication. —Negative effects on family dynamics. —Acne. —Stigma. —Harms/barriers to utilization of care related to psychosocial interventions (e.g., time investment, limited access to trained providers, and lower acceptability based on a misperception that family-focused psychosocial interventions carry implicit judgements about the quality of their parenting). —Study withdrawal due to medication adverse effects.	Unvalidated outcomes measures.
Timing	KQs 1–6. Any length of follow-up.	
Setting	KQs 1–6. Clinical setting, including medical or psychosocial care that is delivered to individuals by clinical professionals (including telehealth), as well as individually focused programs to which clinicians refer their patients; may include classroom settings when intervention is directed to treat disruptive behavior(s) in a specific child (not the whole class) as part of that child's treatment plan.	Exclude school wide or system wide settings (e.g., juvenile justice system) wherein interventions are targeted more widely.
Study Design	Randomized controlled trials (no sample size limit), comparative nonrandomized controlled trials that adjust for confounding variables (N≥100), published in English on or after 1994.	Published before 1994.

Abbreviations: ADHD=Attention-deficit/hyperactivity disorder; ASD=Autism Spectrum Disorder; DBD=Disruptive Behavior Disorders; FDA=U.S. Food and Drug Administration; KQ=Key Question.

Dated: March 30, 2023.

Marquita Cullom,

Associate Director.

[FR Doc. 2023–07129 Filed 4–5–23; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0112]

Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Draft Guidance for Industry; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice announcing the availability of a draft guidance for industry that appeared in the **Federal Register** of February 13, 2023. In that notice, FDA requested comments on the draft guidance for industry entitled ''Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development.'' The

Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice published February 13, 2023 (88 FR 9296). Submit either electronic or written comments by May 15, 2023, to ensure that the Agency considers your comment on this draft guidance before it begins 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–0112 for ''Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Draft Guidance for Industry.'' 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 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: An Massaro, Office of Pediatric Therapeutics, Office of Clinical Policy and Programs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993–0002, 301–467–8507; Gerri Baer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993–0002, 240–402–2865; Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7242, Silver Spring, MD 20993–0002, 240–402–8113; and Vasum Peiris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002, 301–796–6089.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 13, 2023, FDA published a notice announcing the availability of a draft guidance for industry entitled ''Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Draft Guidance for Industry,'' and requested comments on the draft guidance.

Interested persons were originally given until April 14, 2023, to comment on the document. The Agency has elected to extend the comment period so that all interested parties are able to more thoroughly consider the request for input. FDA is extending the comment period for 30 days, until May 15, 2023. The Agency believes that this 30-day extension allows adequate time for interested persons to submit comments.

Dated: April 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07185 Filed 4–5–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0278]

Action Levels for Lead in Food Intended for Babies and Young Children; Draft Guidance for Industry; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the draft guidance entitled ''Action Levels for Lead in Food Intended for Babies and Young Children; Draft Guidance for Industry,'' which was announced in the **Federal Register** of January 25, 2023. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the draft guidance published