(capped at a maximum base amount of $250,000 per violation).

iii. In an egregious case, if the apparent violation is disclosed through a voluntary self-disclosure, the base amount shall be one-half of the statutory maximum penalty applicable to the violation.

iv. In an egregious case, if the apparent violation comes to OEE's attention by means other than a voluntary self-disclosure, the base amount shall be the statutory maximum penalty applicable to the violation.

The following matrix represents the base amount of the civil monetary penalty for each category of violation:

BASE PENALTY MATRIX

		Egregious Case	
		NO	YES
Voluntary Self-Disclosure	YES	(1) One-Half of Transaction Value (capped at $125,000 per violation)	(3) One-Half of Applicable Statutory Maximum
	NO	(2) Applicable Schedule Amount (capped at $250,000 per violation)	(4) Applicable Statutory Maximum

b. Adjustment for Applicable Relevant Factors

The base amount of the civil monetary penalty may be adjusted to reflect applicable Factors for Administrative Action set forth in Section III of these Guidelines. A Factor may result in a lower or higher penalty amount depending upon whether it is aggravating or mitigating or otherwise relevant to the circumstances at hand. Mitigating factors may be combined for a greater reduction in penalty, but mitigation will generally not exceed 75 percent of the base penalty. Subject to this limitation, as a general matter, in those cases where the following Mitigating Factors are present, BIS will adjust the base penalty amount in the following manner:

In cases involving exceptional cooperation with OEE as set forth in Mitigating Factor G, but no voluntary self-disclosure as defined in § 764.5 of the EAR, the base penalty amount generally will be reduced between 25 and 40 percent. Exceptional cooperation in cases involving voluntary self-disclosure may also be considered as a further mitigating factor.

In cases involving a Respondent's first violation, the base penalty amount generally will be reduced by up to 25 percent. An apparent violation generally will be considered a ''first violation'' if the Respondent has not been convicted of an export-related criminal violation or been subject to a BIS final order in five years, or a warning letter in three years, preceding the date of the transaction giving rise to the apparent violation. A group of substantially similar apparent violations addressed in a single Charging Letter shall be considered as a single violation for purposes of this subsection. In those cases where a prior Charging Letter or warning letter within the preceding five years involved conduct of a substantially different nature from the apparent violation at issue, OEE may consider the apparent violation at issue a ''first violation.'' In determining the extent of any mitigation for a first violation, OEE may consider any prior enforcement action taken with respect to the Respondent, including any warning letters issued, or any civil monetary settlements entered into with BIS. When an acquiring firm takes reasonable steps to uncover, correct, and disclose or cause to be disclosed to OEE conduct that gave rise to violations by an acquired business before the acquisition, OEE typically will not take such violations into account as an aggravating factor in settling other violations by the acquiring firm.

iii. In cases involving charges pertaining to transactions where a license would likely have been approved had one been sought as set forth in Mitigating Factor H, the base penalty amount generally will be reduced by up to 25 percent.

In all cases, the penalty amount will not exceed the applicable statutory maximum. Similarly, while mitigating factors may be combined for a greater reduction in penalty, mitigation will generally not exceed 75 percent of the base penalty.

C. Settlement Procedures

The procedures relating to the settlement of administrative enforcement cases are set forth in § 766.18 of the EAR.

Dated: December 22, 2015.

David W. Mills,

Assistant Secretary for Export Enforcement.

[FR Doc. 2015–32606 Filed 12–24–15; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2014–N–1207]

Use of the Term ''Natural'' in the Labeling of Human Food Products; Request for Information and Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for a docket to receive information and comments on the use of the term ''natural'' in the labeling of human food products, including foods that are genetically engineered or contain ingredients produced through the use of genetic engineering. A notice requesting comments on this topic appeared in the **Federal Register** of November 12, 2015. We initially established February 10, 2016, as the deadline for the submission of comments. We are taking this action

in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period for a docket to receive information and comments on the use of the term ''natural'' in the labeling of human food products. We established the docket in a notice published on November 12, 2015 (80 FR 69905). Submit either electronic or written comments to the docket by May 10, 2016.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2014–N–1207 for ''Use of the Term 'Natural' in the Labeling of Human Food Products; Request for Information and Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Margaret-Hannah Emerick, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 12, 2015 (80 FR 69905), we published a notice announcing the establishment of a docket to receive information and comments on the use of the term ''natural'' in the labeling of human food products, including foods that are genetically engineered or contain ingredients produced through the use of genetic engineering. The notice discussed FDA's position regarding the use of the term ''natural'', the events that prompted us to establish a docket to request comment on this issue, and specific questions. We provided a 90-day comment period that was scheduled to end on February 10, 2016.

We received requests for a 90-day extension of the comment period. The requests conveyed concern that the current 90-day comment period does not allow sufficient time to develop meaningful or thoughtful comments to the questions and issues we presented in the notice.

FDA has considered the requests and is extending the comment period for 90 days, until May 10, 2016. We believe that a 90-day extension allows adequate time for interested persons to submit comments.

Dated: December 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32471 Filed 12–24–15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2015–0074; FRL–9940–58–Region 5]

Air Plan Approval; Indiana; Temporary Alternate Opacity Limits for American Electric Power, Rockport

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Indiana State Implementation Plan (SIP), authorizing temporary alternate opacity limits (TAOLs) at the American Electric Power, Rockport (AEP Rockport) facility during periods of unit startup and shutdown. This action is consistent with the Clean Air Act (CAA) and EPA policy regarding emissions during periods of startup and shutdown. Indiana has provided an air quality analysis demonstrating that this revision will continue to protect the applicable National Ambient Air Quality Standards (NAAQS) for fine particulate matter ($PM_{2.5}$) in Spencer County.