Appendix 12

Conventions for Naming Files and Folders in an Electronic Submission

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I.   Purpose of the Conventions for Naming Files and Folders

The purpose of the recommended conventions for naming files and folders in an electronic regulatory submission is to facilitate our storage and retrieval of the files in your submission and, as a result, improve the efficiency of our review of your submission.

II.   General Considerations for Naming Files and Folders

A.   What You Should Do When Naming Files

You should name a file in a way that will help us to see what is in the file and when the file was prepared or submitted. In general, our recommended conventions for naming files vary depending on:

- The type of data or information;

- Whether the data or information is transmitted in a new regulatory submission or in an amendment, update or supplement to a previous regulatory submission;
- The length of the name of the substance that is the subject of the file;
- Whether an acronym, CAS Reg. No., or trade name is associated with the substance that is the subject of the file; and
- Whether the complete document that is the subject of the file exceeds 50 megabytes and, thus, is broken into more than one file.

You should create a file name using both generic elements and specific elements.
- Generic elements relate to the type of information in a file. Examples of generic elements include:
    - The applicable form number;
    - Specifications; and
    - The type of safety study.
- Specific elements relate to your particular submission. Examples of specific elements include:
    - The name of the substance(s) that is/are the subject of the file;
    - The study number (for safety studies); and
    - The date associated with the file.

You should use a combination of initial capitals, underscores and hyphens to separate words or characters in a file name. The conventions we prefer are as follows:
- Use initial capitals to separate multiple words in a generic or specific element. For example:
    - ProposedRegulation
    - StabilityData
    - ShortTermToxicity
    - FishProteinIsolate
    - ChewingGumBase
- Use underscore to separate the various elements of a file name. For example:
    - ProposedRegulation_FishProteinIsolate
- Use hyphens when they are an actual part of the code or name for a generic or specific element
    - Form3480-A
    - Study1234-5
    - Coumarone-IndeneResin
    - 34901-14-9 (A CAS Reg. No.)
- Use hyphens to separate the year, month and day in a date – e.g., 2008-12-30

B.   What You Should Do When Naming Folders

We provide the folder names for most of the folders in the roadmaps. The principal circumstance where you would develop and use a folder name is for the folders associated with specific chemicals in a FCN. In general, to name a folder you should follow the same

recommendations we make for naming a file (e.g., regarding the use of initial capitals, underscores, and hyphens).

The specific conventions we prefer for naming a folder for a chemical (in order of preference) are as follows:
- Use the CAS Reg. No.;
- Use a chemical name (or alternative chemical name) plus the CAS Reg. No. (provided that the chemical name is both well known to scientists and not too long);
- Use the CAS Reg. No. plus a meaningful description of the chemical (such as an abbreviation, a shortened version of the chemical name, or a trade name); or
- Use a meaningful description of the chemical (such as an abbreviation, a shortened version of the chemical name, or a trade name).

C.   What You Should <u>Not</u> Do When Naming Files or Folders

You should <u>not</u>:
- Use the following characters in a file or folder name: / \ * ? : " " < > | + , $.
- Use spaces in a file or folder name.
- Use any terms you view as a trade secret or as confidential in a file or folder name.
- Use any code name or code number in any file or folder name.
- Use more than 150 characters in a file or folder name.

III.   Conventions for Naming Files

A.   Generic Elements

You should use one of the generic elements recommended in this section whenever possible. If none of these generic elements apply to your file, then you should develop and use your own content-specific, succinct word or words to serve as a generic element. In some cases, you may be able to modify one of the recommended generic elements to meet your needs. For example, if you have several files relating to the stability of a substance, you could begin all these files with the word "Stability," followed by one or more words to adequately distinguish the contents of each of these related files.

1.   Generic elements to use when naming files in a FAP, CAP, or CMF

As applicable, you should use the following generic elements when naming files in a FAP, CAP, or CMF:
- Form3503
- CoverLetter
- DesignationOfNondisclosableInformation
- PrescribedFee
- Amendment
- Update
- RedactedBySubmitter

- ProposedRegulation
- ProposedTolerance
- ExemptCertification
- Identity
- UseAndTechnical Effect
- Labeling
- ManufacturingProcess
- Specifications
- ExposureEstimates
- StabilityData
- IntendedEffect
- MigrationData
- AnalyticalMethod
- SafetyNarrative
- EA
- ClaimCategoricalExclusion
- MarketVolume

For the generic elements to use when naming safety studies, see the specific recommendations for combining generic and specific elements to name safety studies in section III.C.3 of this Appendix.

2. *Generic elements to use when naming files in a FCN or PNC*

As applicable, you should use the following generic elements when naming files in a FCN or PNC:

- Form3480
- Form3480-A
- CoverLetter
- DesignationOfNondisclosableInformation
- RedactedBySubmitter
- Identity
- Structure
- IR
- NMR
- MassSpec
- ManufacturingProcess
- RawMaterialSpecs
- Impurities
- Specifications
- MolWeightProfile
- IntendedUse
- TechnicalEffect
- Stability

- MigrationCalculation
- ExposureCalculation
- StabilityStudy
- MigrationStudy
- SafetyNarrative
- CTP
- LiteratureSearch
- EA
- FIFRA Label
- Market Volume

For the generic elements to use when naming safety studies, see the specific recommendations for combining generic and specific elements to name safety studies in section III.C.3 of this Appendix.

3. *Generic elements to use when naming files in a FMF*

You should use the generic elements for naming files in FCNs when submitting a FMF regarding a FCS and the generic elements for naming files in FAPs when submitting a FMF for a substance other than a FCS.

4. *Generic elements to use when naming files in a GRAS notice*

As applicable, you should use the following generic elements when naming files in a GRAS Notice:
- Form3667
- CoverLetter
- DesignationOfNondisclosableInformation
- RedactedBySubmitter
- GRASNotice
- Amendment
- Supplement

5. *Generic elements to use when naming files in a Biotechnology Final Consultation*

As applicable, you should use the following generic elements when naming files in a Biotechnology Final Consultation:
- Form3665
- CoverLetter
- DesignationOfNondisclosableInformation
- RedactedBySubmitter
- Submission

- Amendment
- Supplement

6.   Generic elements to use when naming files in a New Protein Consultation

As applicable, you should use the following generic elements when naming files in a New Protein Consultation:
- Form3666
- CoverLetter
- DesignationOfNondisclosableInformation
- RedactedBySubmitter
- Submission
- Amendment
- Supplement

B.   Specific Elements

1.   Date

You should use the following formats for dates:
- YYYY-MM-DD – Use this format to identify the year, month, and day of the month whenever all three pieces of the date are available.
- Month YYYY – Use this format when only the month and year are available (e.g., for the date of an article published in a journal issued monthly). (When using this format, you should use letters to spell an abbreviation for the month rather than use a number to designate the month – e.g., Feb 2008)
- YYYY – Use this format when only the year is available (e.g., for some publications).

The date you should include in the file name depends on the nature of the file.
- In most cases, include the date you prepared the final file.
- When the subject of the file is an amendment, update, or supplement, include the date of the submission (i.e., the date you include on the applicable form).
- When the subject of the file is a chemistry, safety, or environmental study, include the date the study was completed.
- When the subject of the file is a publication, include the date of the publication.

2.   Name of the Substance

The name you use for the substance that is the subject of a specific file in your submission should be both easy to read and adequate to clearly identify the substance. Below, we list examples of conventions you could use to name a substance, in order of preference:
- The chemical name (when the chemical name is not too long);
- The CAS Reg. No. (or combination of the CAS Reg. No. and an acronym, abbreviation, or trade name) (if more than one CAS Reg. No. is assigned to a particular chemical, you should select one CAS Reg. No. and use it throughout);

- An acronym or abbreviation (e.g., when the chemical name is long and well-suited to being recognized by an acronym or abbreviation); and
- A descriptive trade name or descriptive term.

C.   Combining Generic Elements and Specific Elements to Name a File

1.   General recommendations for combining generic and specific elements

In most cases, you should order the elements in the file name as follows:
- Begin with the generic element;
- Add one or more applicable specific elements; and
- End with the applicable date.

Exceptions include:
- Files included in amendments, updates, and supplements. You should begin the names of these files with the date of the submission. Doing so will enable us to place these files in chronological order in our database and will help our reviewers to clearly distinguish files submitted with the original regulatory submission from files submitted later.
- Large documents that you submit as more than one file because a single file containing the complete file would exceed 50 MB. You should end the file name of each individual file derived from the complete document with the inclusive page numbers contained within the file (e.g., pp. 1-250, pp. 251-400). You should place the applicable date immediately before the page numbers.

2.   Specific recommendations for naming chemistry-related files

You should name a chemistry-related file as follows:
- Begin the file name with a generic element (e.g., Identity, ManufacturingProcess, Stability);
- Add the name of the test substance and other specific elements that would help describe the contents of the file;
- Add the applicable date (e.g., the date you prepared the final file, or the date a study was completed); and
- Add the inclusive page numbers contained in the file (when a complete chemistry document would exceed 50 megabytes and, thus, the complete document is broken into more than one file).

Examples:

Identity_NewSweetener_2009-01-30.pdf

Migration_PolymerX_2008-11-05

3.   *Specific recommendations for naming safety studies*

You should name a file containing a safety study as follows:
- Begin the file name with a generic element (e.g., Ames, SubchronicToxicity; see the list below);
- Add the Study Number (in the format *Study####)*;
- Add the name of the applicable substance;
- Add the name of the animal species (for studies conducted in animals);
- Add the route of administration (for studies conducted in animals or humans);
- Add the date the study was completed; and
- Add the inclusive page numbers contained in the file (when a file containing the complete study would exceed 50 megabytes and, thus, the complete study is broken into more than one file).

As applicable, you should use the following generic elements when naming files associated with safety studies:
- Ames
- ChromosomeAberration
- InVivoMicronucleus
- MouseLymphoma
- SisterChromatidExchange
- UnscheduledDNASynthesis
- ShortTermToxicity
- SubchronicToxicity
- ChronicToxicity
- Carcinogenicity
- CarcinogenicityWithInUteroExposure
- ChronicToxicity&Carcinogenicity
- ReproductiveToxicity
- ReproductiveToxicityWithTeratology
- Teratology
- Immunotoxicity
- MetabolismAndPharmacokinetic
- Neurotoxicity
- NeurobehavioralToxicity
- HumanClinical
- Nutrition
- Epidemiology
- OcularIrritation
- Dermal

Examples:

AcuteToxicity_Study1234-6_NewSweetener_Rats_Oral_2008-11-03.pdf

SubchronicToxicity_Study1234-6_NewSweetener_Rats_Oral_2008-11-03_pp.1-250.pdf

SubchronicToxicity_Study1234-6_NewSweetener_Rats_Oral_2008-11-03_pp.251-400.pdf

4.   Specific recommendations for naming environmental studies

You should name a file containing an environmental study as follows:
- Begin the file name with a succinct name for the study;
- Add the Study Number (or other study identifier) (in the format *Study####*);
- Add the name of the applicable substance;
- Add the date the study was completed; and
- Add the inclusive page numbers contained in the file (when a file containing the complete study would exceed 50 megabytes and, thus, the complete study is broken into more than one file).

Example:

UltimateBiodegradabilityTwoPhaseClosedBottleTest_StudyR-1134_PolymerX_2008-11-07.pdf

5.   Specific recommendations for literature references

You should name a file containing a literature reference as follows:
- Begin the file name with an abbreviated title;
- Add the name of the applicable substance; and
- Add abbreviated citation information, ending with the date.

Example:

MutagenicityPotentialOf 99Chemicals(excerpts34901-14-9)_JBiolTox(22)_Dec1983.pdf

6.   Specific recommendations for GRAS notices, Biotechnology Final Consultations, and New Protein Consultations

You should name a file contained in a GRAS notice, Biotechnology Final Consultation, or New Protein Consultation as follows:
- Begin the file name with the applicable generic element;
- Add the name of the applicable substance; and
- End with the applicable date.

Examples:

Form3667_NewSweetener_2009-01-30.pdf

GRASNotice_NewSweetener_2009-01-30.pdf

Submission_NewCornVariety_2009-01-30.pdf

Submission_ProteinX_2009-01-30.pdf

7.   *Specific recommendations for amendments, updates, and supplements*

You should always begin the file name of any file submitted as an amendment, update, or supplement with the date the amendment, update, or supplement is transmitted.

For some files, the name of the file will have two dates. For example:
- The file name for a subchronic toxicity study that was completed on December 7, 2008 and transmitted to us in an amendment dated January 30, 2009, would begin with 2009-01-30 and include 2008-12-07 at the end of the file (or just before the inclusive page numbers, if the study report is so large that it is broken into more than one file).

   Example:
   2009-01-30_SubchronicToxicity_Study5567_ EmulsifierX_Rats_OralGavage_ 2008-12-07.pdf

- The file name for a publication that is dated November, 2008 and transmitted to us in an amendment dated January 16, 2009 would begin with 2009-01-16 and end with Nov 2008.

8.   *Specific recommendations for naming redacted files*

The specific recommendations for naming a redacted file depend on whether the file is submitted with a new regulatory submission or with an amendment, update or supplement to an existing regulatory submission.

- New regulatory submission: You should begin the file name of a redacted electronic copy of a file transmitted in a new regulatory submission with "RedactedBySubmitter," followed by the complete name of the original, unredacted file.

   Example: *RedactedBySubmitter_GRASNotice_NewSweetener_2008-12-01.pdf*

- Amendment, update or supplement to an existing regulatory submission: You should begin the file name of a redacted electronic copy of a file transmitted in an amendment, update or supplement with the date of the submission, followed by "RedactedBySubmitter," followed by the complete name of the original, unredacted file.

Example:

2009-03-01_RedactedBySubmitter_GRASNotice_ManufacturingProcess_Sweetener.pdf