Status: Final

Form Date: 12-FEB-14

Question 1: OPDIV
Question 1 Answer: FDA

Question 2: PIA Unique Identifier (UID):
Question 2 Answer: P-5100023-810413

Question 2A: Name:
Question 2A Answer: Chemical Evaluation and Risk Estimation System

Question 3: Which of the following objects does this PIA Cover?
Question 3 Answer: Major Application

Question 3A: Identify the Enterprise Life-Cycle Phase of the System:
Question 3A Answer: Operations and Maintenance

Question 3B: Is this a FISMA Reportable System?
Question 3B Answer: No

Question 4: Does the system include a publicly available Web interface?
Question 4 Answer: No

Question 5: Identify the operator
Question 5 Answer: Agency

Question 7: Is this a new or existing system
Question 7 Answer: Existing

Question 8: Does the system have Security Authorization (SA)?
Question 8 Answer: Yes

Question 8A: Date of Security Authorization
Question 8A Answer: 02-JAN-13

Question 8B-1: Planned date of Security Authorization - Not Applicable
Question 8B-1 Answer: Not Checked

Question 9: PIA Validation (PIA Refresh/Annual Review)
Question 9 Answer: Checked

Question 10: Describe in further detail any changes to the system that have occurred since the last PIA.
Question 10 Answer: No changes.

Question 11: Describe the purpose of the system.
Question 11 Answer: The FDA's Center for Food Safety and Applied Nutrition (CFSAN) uses the Chemical Evaluation and Risk Estimation System (CERES) as a data management and storage system. It provides decision support tools for both pre-market and post-market safety assessments of food additives and food contact substances as well as for potential contamination issues. CERES provides a single unified data repository that compiles available information on a substance, including: chemical structures and properties, regulation records, toxicity studies, and other biological screening assays.

Question 12: Describe the type of information the system will collect, maintain (store), or share.
(Subsequent questions will identify if this information is PII and ask about the specific

data elements.)
Question 12 Answer: CERES collects and stores chemical, toxicological and regulatory data.

It stores chemical data, including:
- Chemical structure,
- Chemical names,
- Chemical annotations, and
- Chemical record identifiers (Chimical Abstract Service (CAS) and CAS-like registry numbers, European Inventory of Existing Commercial Chemical Substances numbers, Unique Ingredient Identifier codes).

CERES stores toxicological data, including:
- Studies from peer reviewed journals, and
- Toxicological studies harvested from US FDA CFSAN Office of Food Additive Safety (OFAS) submissions.

CERES also stores regulatory data, limited to US FDA CFSAN OFAS submissions:
- submission type and submission number,
- date received,
- date completed,
- submission title,
- chemicals associated with a submission, and
- Code of Federal Regulation (CFR) provision associated with a submission.

Question 13: Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.
Question 13 Answer: CERES streamlines key tasks and integrates disparate sources of data currently available at CFSAN. It is a chemocentric system which supports decisions involved in CFSAN's Office of Food Safety's pre-market reviews and post-market surveillances. CERES modernizes and expands CFSAN's Priority-Based Assessment of Food Additives system (PAFA)* by enlarging toxicology databases, allowing for real-time data updating, and centralizing data currently stored in numerous tables, databases and electronic files. CERES also enhances the agency response to contamination issues. It provides a single data repository capable of compiling all related information on a substance and analyzing data on related substances in order to identify all potential safety issues. The system also enables all response personnel to have access to the complete set of data for a more efficient and effective analytical response.

*The agency decommissioned the PAFA system on April 12, 2013. FDA has incorporated the entire PAFA database, including chemical and toxicity data, into the CERES database.

Question 14: Does the system collect, maintain, use, or share PII?
Question 14 Answer: No