Exhibit 6-1B

Case Initiation Memorandum Outline

POINTS OF CONTACT List of Primary Center, District and OEIO-DE contacts with phone numbers (on the top of the very first page). Identify any OCC attorneys who have been consulted on the case.

****NOTE THAT THE FORMAT MUST BE AS A NOTE/REFERRAL TO OCC TO ASSERT THE APPROPRIATE PRIVILEGES TO PROTECT IT FROM DISCOVERY**

(Attachment A "LEAD "ASSIGNMENT to CIM ELEMENTS)

- **BRIEF EXECUTIVE SUMMARY (DESCRIPTION OF EVIDENCE)**: limit to 3 or 4 sentences to identify type of product, conduct and nature of the case. Just need the big picture, for example: "This is a proposed permanent injunction against a cheese manufacturer whose products have been found to be contaminated with listeria in the past and who has a lengthy history of egregious sanitation and cGMP deficiencies" OR "This is a proposed mass seizure of food products stored in a facility infested by rodents."
- **PRODUCT INFORMATION** (Obtain this information from the Center)
  - Examples: Approvals (IND, NDA, 510(k), PMA, IDE, Licensed, OTC Monograph), if relevant to charges
  - Product Classification or Type e.g., Rx, OTC, Device Class, if relevant
  - Product Labels and Labeling (hyperlink to Photos and Draft Complaint)
- **ORGANIZATIONAL CHART** (hyperlink to EIR and/or Org. Chart)
  - Include a BRIEF description of most responsible person(s)
  - Identify proposed defendants including a hyperlink to evidence used to support that this is most responsible person (hyperlink to affidavit and articles of incorporation).
  - Name of current counsel, if known
  - Corporate Relationships (subsidiaries/parent companies)
- **CURRENT INSPECTION**
  - Rather than a "cut and paste" of the FDA 483 observations, list the most significant observations/violations categorized by the type of violation (e.g., filth, cGMP, labeling violations etc.,) with reference or hyperlink to details in the EIR AND to the RELEVANT exhibits (Please do not reference ALL EIR exhibits). <INSERT AUTHOR(s) NAME and DISTRICT/CENTER/DIVISION.

- FURTHER GUIDANCE: FDA 483 observation would be explained within the context of the larger system to frame its significant impact on production, product safety and public health. Provide critical insight and context for the observations explaining its impact on the product or process. For example, rather than "we observed a hole in the roof of the facility," explain "we observed water dripping onto the food being processed from a hole in the facility's roof. When including hyperlinks to the evidence please identify the location of key information supporting the FDA 483 observation. For example, the hyperlink to a 42 page laboratory analysis worksheet would identify the page(s) where key evidence is located.

- All documented evidence should be in finalized form (including signatures, as appropriate) whenever possible.

- If the EIR has not been finalized provide a "separate" document that captures this information. <INSERT AUTHOR(s) NAME, DISTRICT/CENTER/DIVISION>

- FDA 483 Observation Table (Tables of Evidence/Attachment B) if the firm has offered to correct the violations, explain the impact on the firm's/product's state of compliance, the risk to public health risk and the regulatory strategy. <INSERT AUTHOR(s) NAME and DISTRICT/CENTER/DIVISION>

- Comparison of Firm's Repeat Observations (Tables of Evidence/Attachment B). When possible, include a table with observations from past inspections to demonstrate recurring violations (rather than a narrative of each inspection). Insert hyperlinks in the table or "list of observations" in the report and the exhibits<INSERT AUTHOR(s)NAME and DISTRICT/CENTER/DIVISION>

- **CENTER OFFICE OF COMPLIANCE CONCURRENCE AND EXPERT INFORMATION**
  <INSERT AUTHOR(s) NAME and CENTER/DIVISION>

  - Charges that the Center preliminarily supports (to be later confirmed through technical/expert support memorandum) public health significance of violations<INSERT AUTHOR(s) NAME and CENTER/DIVISION>

  - Weaknesses- please include Center's weaknesses in the combined "ANTICIPATED DEFENSES/POTENTIAL WEAKNESSES"* IN THE SECTION BELOW

  - Preliminary Risk Assessment (Counter-arguments to Public Health significance) (to be confirmed through technical/expert support memorandum) <INSERT AUTHOR(s) NAME and CENTER/DIVISION

  - The Center's review of the Firm's FDA 483 response. If incomplete, the status is indicated in Attachment B table, "Firm's Stated or Observed Corrective Actions."

<INSERT AUTHOR(s) NAME and CENTER/DIVISION.

- List of most similar precedent cases (Seizure or Injunction or CMP)
- The Center's technical /expert evaluations (e.g., GMP; new drug) (separate) is needed but <u>if incomplete would not delay the issuance of the CIM</u> <INSERT AUTHOR(s) NAME and CENTER/DIVISION

  - Table format (Attachment B) for e.g., GMP violations is VERY useful; effective and efficient way to compare current violations with those seen in the past, Focus on major violations, categories of violations, and link observations to particular locations and dates. If more than one, identify the expert (Attachment B) with the particular charges for which each will testify<INSERT AUTHOR(s) NAME and CENTER/DIVISION>
  - If in-house experts, provide a CV and direct phone number and a summary of the expert's views, prioritizing the supportable violations in order of severity and explaining the significance of each violation
  - For outside experts, provide a CV, email address, and phone number, and confirmation that the expert has been retained and commitments as to date we can expect expert's evaluation if not already completed.
  - Results of database search if charge involves filing or registering with FDA or obtaining approval from the agency or literature search (GRAS/E) when new drug charges are included <INSERT AUTHOR(s) NAME and CENTER/DIVISION>
  - HHE if applicable <INSERT AUTHOR(s) NAME and CENTER/DIVISION>
  - Review by drug shortage staff or evaluated as medically necessary (device) when appropriate (Center) <INSERT AUTHOR(s) NAME and CENTER/DIVISION>

- Judicial District
- Interstate commerce, hyperlink the key single documents (not an entire CR e.g., doc. Sample/product label) Specify whether the hyperlinked documents are for finished products or components (and if components, the names of the associated finished products); <INSERT AUTHOR(s) NAME and DISTRICT/CENTER/DIVISION>
- Complaints-Summary of any consumer complaints and/or injuries or whistleblower reports<INSERT AUTHOR(s) NAME and DISTRICT/CENTER/DIVISION>
- **REGULATORY HISTORY** (hyperlink to finalized documents, where possible and appropriate) <INSERT AUTHOR(s) NAME and DISTRICT/CENTER/DIVISION>

  - BRIEF SUMMARY of inspection history including inspection classification with emphasis on recurring violations (should be no more than one or two paragraphs) (Cross

Reference TABLES OF EVIDENCE, Attachment B as needed)

- Recalls (most recent first and should identify products)
- Warning or Untitled Letters AND response(s) (Cross Reference TABLES OF EVIDENCE, Attachment B as needed)
- Regulatory meeting minutes
- Written responses from firm (to inspections, 483s, warning or untitled letters) (Cross Reference TABLES OF EVIDENCE/ Attachment B as needed)
- FDA evaluation of firm's responses (Cross Reference TABLES OF EVIDENCE/ Attachment B as needed)
- Other written correspondence from firm or its counsel re: the violations at issue. Please include a table (Cross Reference TABLES OF EVIDENCE/Attachment B as needed) identifying any correspondence received from the firm
- Please include a table with the firms corrective actions (Cross Reference TABLES OF EVIDENCE/Attachment B) e.g., stated in the firm's 483 response or other correspondence or during the re-inspection) as well as FDA's evaluation of the correction (whether it was adequate <INSERT AUTHOR(s) NAME and CENTER/DIVISION>

- Relief requested (Use drafts from RPM as a starting point and filed cases as models) although we will rely on OCC to draft the consent decrees, there are certain substantive provisions which must be drafted by the centers and districts, as they describe the particular technical and scientific steps that must be taken to bring an operation into compliance. We are including samples in the RPM Chapter 6 of usual requirements for a variety of FDA's more typical types of cases. Please note that these are examples only, not boilerplate, and are intended to set out the level of detail that the centers and districts will need to contribute to the scientific/technical aspects of the relief, in lieu of preparing a draft consent decree. The assigned center and district personnel must adapt these provisions to the particular circumstances of each case. In reviewing these samples, employees are not limited to linking the specific relief to a particular type of case. For example, in these examples, audit requirements are set out in the CGMP sections, but there may be situations in which a food sanitation case will need that type of relief. Similarly, the examples do not encompass every type of violation seen in FDA's cases, but they should provide sufficient guidance to assist in generating the operative portion of the decree in cases involving other types of violations <INSERT AUTHOR(s) NAME and DISTRICT/CENTER/DIVISION>

    - Proposed charges and consent decree provisions (Reference the RPM) Look at all the CDs to pick and choose what will get them to the goal (take a look at the precedent cases)

- ANTICIPATED DEFENSES [DISTRICT/CENTER/OCC]: Any potential weaknesses in case including defense's already known or advanced by the firm or its counsel. Both the District and the Center need to provide input on potential weaknesses for the case including any weaknesses that were discussed during the Preliminary Assessment Call. <INSERT AUTHOR(s) NAME and DISTRICT/CENTER/DIVISION>

- Other reports submitted (or confirmation that none were filed) such as Field Alert reports, adverse event reports, medical device reports, post marketing reports. <INSERT AUTHOR(s) NAME and DISTRICT/CENTER/DIVISION>

Attachment A

LEAD ASSIGNMENTs to CIM ELEMENTS

	ELEMENT	**LEAD**
1	**POINTS OF CONTACT** List of Primary Center, District and OEIO-DE contacts with phone numbers (on the top of the very first page). Identify any OCC attorneys who have been consulted on the case.	
2	**BRIEF EXECUTIVE SUMMARY (DESCRIPTION OF EVIDENCE) (**limit to 3 or 4 sentences) to identify type of product, conduct and nature of the case. Just need the big picture, for example: "This is a proposed permanent injunction against a cheese manufacturer whose products have been found to be contaminated with listeria in the past and who has a lengthy history of egregious sanitation and cGMP deficiencies" OR "This is a proposed mass seizure of food products stored in a facility infested by rodents ."	
3	**PRODUCT INFORMATION (Obtain information from the center)**	
	Examples: Approvals [IND, NDA, 510(k), PMA, IDE, Licensed, OTC Monograph], if relevant to charges	
	Product Classification or Type e.g., Rx, OTC, Device Class, if relevant	
	Product Labels and Labeling (hyperlink to Photos and Draft Complaint)	
4	**ORGANIZATIONAL CHART** (Hyperlink to EIR and/or Org. Chart)	
	Include a BRIEF description of most responsible person(s)	
	Identify proposed defendants including a hyperlink to evidence used to support that this is most responsible person (hyperlink to affidavit and articles of incorporation)	
	Name of current counsel, if known	
	Corporate Relationships (subsidiaries/parent companies)	

	ELEMENT	LEAD
5	**CURRENT INSPECTION**	
	Rather than a "cut and paste" of the FDA 483 observations, list the most significant observations/violations categorized by the type of violation (e.g., filth, cGMP, labeling violations etc.,) with reference or hyperlink to details in the EIR AND to the RELEVANT exhibits (Please do not reference ALL EIR exhibits). FURTHER GUIDANCE: FDA 483 observation would be explained within the context of the larger system to frame its significant impact on production, product safety and public health. Provide critical insight and context for the observations explaining its impact on the product or process. For example, rather than "we observed a hole in the roof of the facility," explain "we observed water dripping onto the food being processed from a hole in the facility's roof. When including hyperlinks to the evidence please identify the location of key information supporting the FDA 483 observation. For example, the hyperlink to a 42 page laboratory analysis worksheet would identify the page(s) where key evidence is located	
	If the EIR has not been finalized provide a "separate" document that captures this information	
	FDA 483 Observation Table (Tables of Evidence/Attachment B) if the firm has offered to correct the violations, explain the impact on the firm's/product's state of compliance, the risk to public health risk and the regulatory strategy.	
	Comparison of Firm's Repeat Observations (Tables of Evidence/Attachment B). When possible, include a table with observations from past inspections to demonstrate recurring violations (rather than a narrative of each inspection). Insert hyperlinks in the table or "list of observations" in the report and the exhibits	

	ELEMENT	LEAD
6.	**CENTER OFFICE OF COMPLIANCE CONCURRENCE AND EXPERT INFORMATION**	
	Charges that the Center preliminarily supports (to be later confirmed through technical/expert support memorandum) public health significance of violations	
	Please include Center's weaknesses in the combined "CENTER/DISTRICT POTENTIAL WEAKNESSES"* section below	
	Preliminary Risk Assessment (Counter-arguments to Public Health Significance) (to be confirmed through technical/expert support memorandum)	
	The Center's review of the Firm's FDA 483 response. If incomplete, the status is indicated in Attachment B (table), "Firm's Stated or Observed Corrective Actions."	
	List of most similar precedent cases (Seizure or Injunction or Civil Money Penalty)	
	The Center's technical /expert evaluations (e.g., GMP; new drug) (separate) is needed but if incomplete would not delay the issuance of the CIM Expert Evaluations (e.g., GMP; new drug, GRAS/E,) –vary with type of case. If more than one, identify the expert (Attachment B) with the particular charges for which each will testify.	
	If in-house experts, provide a CV and direct phone number and a summary of the expert's views, prioritizing the supportable violations in order of severity and explaining the significance of each violation	
	For outside experts, provide a CV, email address, and phone number, and confirmation that the expert has been retained and commitments as to date we can expect expert's evaluation if not already completed.	
	Results of database search if charge involves filing or registering with FDA or obtaining approval from the agency or literature search (GRAS/E) when new drug charges are included	

	ELEMENT	**LEAD**
	HHE if applicable	
	Review by drug shortage staff or evaluated as medically necessary (device) when appropriate (Center)	
7.	**JUDICIAL DISTRICT**	
8.	**INTERSTATE COMMERCE** Hyperlink the key single documents (not an entire CR e.g., doc. Sample/product label) Specify whether the hyperlinked documents are for finished products or components (and if components, the names of the associated finished products)	
	Finished Product Interstate Documentation	
	Component Interstate Documentation	
9	**SHORTAGE REVIEW** by drug shortage staff or evaluated as medically necessary (device) when appropriate	
10	**COMPLAINTS** Summary of any consumer complaints and/or injuries or whistleblower reports	
11	**REGULATORY HISTORY** (hyperlink to finalized documents, where possible and appropriate)	
	Brief Summary of inspection history including inspection classification with emphasis on recurring violations (should be no more than one or two paragraphs) (Cross Reference TABLES OF EVIDENCE, Attachment B as needed)	
	Recalls (most recent first and should identify products)	
	Warning or Untitled Letters AND response(s) (Cross Reference TABLES OF EVIDENCE, Attachment B as needed)	
	Regulatory meeting minutes	

	ELEMENT	**LEAD**
	Written responses from firm (to inspections, 483s, warning or untitled letters) (Cross Reference TABLES OF EVIDENCE/ Attachment B as needed)	
	FDA evaluation of firm's responses (Cross Reference TABLES OF EVIDENCE/ Attachment B as needed)	
	Other written correspondence from firm or its counsel re: the violations at issue. Please include a table (Cross Reference TABLES OF EVIDENCE/Attachment B as needed) identifying any correspondence received from the firm	
	Please include a table with the firms corrective actions (Cross Reference TABLES OF EVIDENCE/Attachment B) e.g., stated in the firm's 483 response or other correspondence or during the re-inspection) as well as FDA's evaluation of the correction (whether it was adequate	
12	**RELIEF REQUESTED** (Use drafts from RPM as a starting point and filed cases as models) Specific relief the Center and District seeks; e.g., stop distribution, initiate a recall, hire consultant. repair facility	
	Proposed Consent Decree Charges AND consent decree provisions	
13	**ANTICIPATED DEFENSES [DISTRICT/CENTER/OCC]** Any potential weaknesses in case including defense's already known or advanced by the firm or its counsel. Both the District and the Center need to provide input on potential weaknesses for the case including any weaknesses that were discussed during the Preliminary Assessment Call.	
14	**OTHER REPORTS SUBMITTED** (or confirmation that none were filed) such as Field Alert reports, adverse event reports, medical device reports, post marketing reports.	

Attachment B

TABLES OF EVIDENCE

District's FDA 483 Observation Table (Current Inspection) (Example)

483 Observation	Citation	Supporting Documents (Hyperlink)	

District's Comparison of Firm's Repeat Observations (Regulatory History) (Example)

Observation	Inspection #1 [DATE]	Inspection #2 [DATE]	Inspection #3 [DATE]
	FDA 483 # [ ]	FDA 483 # [ ]	FDA 483# [ ]

Center's Significant FDA 483 Observations and Identified Expert Table

483 Observation (Prioritized by Severity)	Citation	Center Supported/Not Supported	Expert Identified (if Center Supported)

Correspondence Received from the Firm (Example)

Correspondence by Firm or its Agents	District Review	Center Review	Did the FDA Respond (Yes or No)	Date FDA Responded
[DATE] & Hyperlink to Correspondence	[DATE] & Hyperlink to review memo or email	[DATE] & Hyperlink to review memo or email		[DATE] & Hyperlink to FDA response

Firm's Stated or Observed Corrective Actions (Example)

FDA 483 Observation # [& Date Observed by FDA]	Firm's Stated Correction	District Evaluation of the Correction	Center Evaluation of the Correction