

Formulating a Blueprint Letter in Response to Facility Document Submissions

- 1.** Use the appropriate references, as noted in the footer of these instructions, to ensure each facility document submission is complete and correct.
- 2.** Ensure that the firm has sufficiently addressed any concerns listed in a CVB blueprint letter previously sent to the firm.
- 3.** Use the blueprint letter template (**ICTEM0003**) as the standard template for responding to all facility document submissions, other than preliminary documents. Preliminary documents are not stamped. A written response to preliminary facility document submissions may be made using CVB letter template (**ICTEM0001**). Any preliminary facility documents will be retained by the CVB for future reference and filed with CVB's response.
- 4.** Four options exist for formatting a blueprint letter in response to facility document submissions:
 - a) Approve all documents submitted without exception.
 - b) Approve documents with pen-and-ink changes and/or requesting the firm to make changes at their next revision of the facility document. The firm should be called prior to making pen-and-ink changes to ensure changes/additions to be made are correct. Changes are to be made in red ink, initialed, and dated.
 - c) Approving some of the documents while sending some back unprocessed for revision.
 - d) Rejecting all documents submitted and sending all back for revision.
- 5.** Both options a and b are encouraged whenever possible. Consider using b in situations where the firm was unaware of what is expected at the time of the submission and pen-and-ink corrections can be easily made. Option c may be most beneficial when a large number of document pages are submitted, and only a small number of pages require revision. Option d is used when multiple problems exist with the documents.
- 6.** Recurring errors in the documents should be summarized at the end of the blueprint letter under the heading Additional Comment(s), rather than placed under each document heading. For example, the plot plan, plot plan legend, and blueprint legend list the wrong supersedes date.
- 7.** Only respond to one facility document submission (can be multiple documents per site) in a single blueprint letter.
- 8.** Draft blueprint letter is reviewed by the Facilities Manager, or Inspection Section Leader, prior to presenting to a BCA. Corrections will be made on the draft by either

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person listed above. BCA will ensure corrections are made and approval has been given prior to finalizing the letter.

- 9.** When a complete revision of the legends is submitted, state Complete Revision in the place of a specific supersedes date. Complete revisions entail changing multiple pages, or the entire legend rather than a mere page change.
- 10.** Summary of changes submissions are stamped, but not included in the blueprint letter.
- 11.** Ensure the proper facility address is included in the blueprint letter for the documents submitted; full street address followed by city and state (spell out), no zip.
- 12.** When the firm submits more than two copies of a document, state in the letter under the Additional Comments section that in the future it is only necessary for the firm to submit two copies of each document. In the closing paragraph, state how many copies (number over two) are being returned unprocessed. In some instances the firm may require more than two copies of the facility documents. This should be explained in their cover letter.
- 13.** Identify each document page as the firm identifies them; for example, page ii, page 1 of 1, page 2, sheet 1 of 1, etc. Each legend page should be numbered.
- 14.** List any discrepancy and corrective action under each document, followed by the 9 CFR reference. Number each discrepancy if more than one.
- 15.** Add the heading to each additional page if items extend to multiple pages. Exclude the “Dated” and “Supersedes Stamp Date” portion of the heading (keep the “Item” portion) for all documents returned unprocessed. See the asterisked (*) items below for examples.
- 16.** Leave a space between each document listed under the “item” heading with the exception as noted in format (c) below.
- 17.** One of the four standard formats listed below should be used for all facility document letters:

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a) Format for facility documents **approved without exception**:

Please refer to the facility documents received reviewed for compliance under 9 CFR Part 108 and have been filed today without exception.

<u>Item*</u>	<u>Dated*</u>	<u>Supersedes Stamp Date*</u>
1234 Transylvania Dr. Albany, California		
Table of Contents pages ii-iii	XXXX	10APR2007
Plot Plan	XXXX	08JAN2007
Plot Plan Legend pages 1-2	XXXX	08JAN2007
Blueprint, Building 1 page 1 of 1	XXXX	01JUL2003
Blueprint, Building 2 page 1 of 1	XXXX	08JAN2007
Blueprint Legend, Building 1 pages 1-27	XXXX	15JUN2005
Blueprint Legend, Building 2 pages 1-22	XXXX	15JUN2005
Blueprint Legend, Building 1 Appendix 1, Decontamination Procedures & Other Precautions Against Cross Contamination pages 1-2	XXXX	15JUN2005
Blueprint Legend, Building 1 Appendix 2, List of Fractions pages 1-3	XXXX	15JUN2005

One stamped copy of each of the above documents is returned for your files and one stamped copy has been retained by the Animal and Plant Health Inspection Service.

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b) Format for facility documents **approved with pen-and-ink corrections, and required changes to be made at the next revision of the facility documents. Add pen-and-ink changes and next revision comments under the appropriate item. Make pen-and-ink changes in red:**

Please refer to the facility documents received reviewed for compliance under 9 CFR Part 108 and have been filed today with the pen-and-ink changes I discussed with you during our June 18, 2008, telephone conversation. During our conversation, we also discussed changes to be made at the next revision of the facility documents.

<u>Item</u>	<u>Dated</u>	<u>Supersedes Stamp Date</u>
1234 Transylvania Dr. Albany, California		
Table of Contents pages ii-iii	XXXX	10APR2007
Plot Plan	XXXX	08JAN2007
Plot Plan Legend pages 1-2	XXXX	08JAN2007
Blueprint, Building 1 page 1 of 1	XXXX	01JUL2003
The compass point is not shown. The compass point should be added to the Building 1 Blueprint at the next revision of the facility documents. [Reference: 9 CFR 108.4(h)]		
Blueprint, Building 2 page 1 of 1	XXXX	08JAN2007
Blueprint Legend, Building 1 pages 1-27	XXXX	15JUN2005
Blueprint Legend, Building 2 pages 1-22	XXXX	15JUN2005

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<u>Item</u>	<u>Dated</u>	<u>Supersedes Stamp Date</u>
Blueprint Legend, Building 1 Appendix 1, Decontamination Procedures & Other Precautions Against Cross Contamination pages 1-2	XXXX	15JUN2005
Blueprint Legend, Building 1 Appendix 2, List of Fractions pages 1-3	XXXX	15JUN2005

Additional Comment:

The incorrect supersedes date was used for the plot plan, Building 1 and Building 2 Blueprints, and Building 2 Blueprint Legend. For future facility document revisions the supersedes date used to identify what is being superseded is the date stamped within the blue "Filed with the USDA" box at the bottom of each page of the facility documents. A pen-and-ink correction was made.
[Reference: 9 CFR 108.6(a)]

One stamped copy of each of the above documents is returned for your files and one stamped copy has been retained by the Animal and Plant Health Inspection Service.

c) Format for approving some facility documents, while sending the remaining documents back unprocessed.

Please refer to the facility documents received reviewed for compliance under 9 CFR Part 108 and have been filed today without exception.

<u>Item</u>	<u>Dated</u>	<u>Supersedes Stamp Date</u>
1234 Transylvania Dr. Albany, California		
Table of Contents pages ii-iii	XXXX	10APR2007
Plot Plan	XXXX	08JAN2007

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<u>Item</u>	<u>Dated</u>	<u>Supersedes Stamp Date</u>
Plot Plan Legend pages 1-2	XXXX	08JAN2007
Blueprint, Building 1 page 1 of 1	XXXX	01JUL2003
Blueprint, Building 2 page 1 of 1	XXXX	08JAN2007
Blueprint Legend, Building 1** pages 1-245	XXXX	15JUN2005
Blueprint Legend, Building 1** pages 247-256	XXXX	15JUN2005
Blueprint Legend, Building 2 pages 1-143	XXXX	15JUN2005
Blueprint Legend, Building 1 Appendix 1, Decontamination Procedures & Other Precautions Against Cross Contamination page 1	XXXX	15JUN2005
Blueprint Legend, Building 1 Appendix 2, List of Fractions pages 1-3	XXXX	15JUN2005

One stamped copy of each of the above documents is returned for your files and one stamped copy has been retained by the Animal and Plant Health Inspection Service.

**Note, not separated by a space as both legends are for Building 1. Suggests still talking about the same thing.

The following documents have been reviewed for compliance under 9 CFR Part 108 and are being returned unprocessed. Please make the necessary revisions and return to the CVB for further review (may want to put a time frame in here, for example, if tied in to an inspection action item).

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Item

Blueprint Legend, Building 1
page 246

The use of Room 121 was not described in the Building 1 Blueprint Legend.
[Reference: 9 CFR 108.5(b)(1)]

Blueprint Legend, Building 1
Appendix 1,
Decontamination
Procedures & Other Precautions Against
Cross Contamination
page 2

During the November, 2006, in-depth inspection, we observed that the firm was performing sanitation procedures in a thorough manner; however, the stamped facility documents do not adequately describe the sanitation procedures being performed in the filling suite, Room 222, Building 1.
[Reference: 9 CFR 108.5(b)(1)]

Additional Comment:

Additional information for preparing facility documents can be found in 9 CFR 108 and Veterinary Services Memorandum 800.78. These documents are available on the CVB website at:
http://www.aphis.usda.gov/animal_health/vet_biologics/vb_regs_and_guidance.shtml.

If you have any questions regarding this matter, please contact me at (515) 337-6100.

d) Format for **sending all documents back unprocessed**.

Please refer to the facility documents received reviewed for compliance under 9 CFR Part 108 and are being returned unprocessed. Please make the necessary revisions and return to the CVB for further review.

Item

1234 Transylvania Dr.
Albany, California

Table of Contents
pages ii-iii

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Item

Plot Plan

1. The properties adjacent to Establishment 4987 are not listed on the plot plan. [Reference: 9 CFR 108.3(e)]
2. The boundaries of the premises are not identified. [Reference: 9 CFR 108.3(b)]

Plot Plan Legend

pages 1-2

The functions performed in each building shown on the plot plan are not described in the plot plan legend. [Reference: 9 CFR 108.5(a)(1)]

Blueprint, Building 1

page 1 of 1

The autoclave and biological safety cabinet in Room 24 are listed as stationary equipment in the Building 1 Blueprint Legend, but, are not shown in the Building 1 Blueprint. [Reference: 9 CFR 108.4(f)]

Blueprint, Building 2

page 1 of 1

1. Building 2 is a two story building; however, the firm did not supply a blueprint for the second story. [Reference: 9 CFR 108.4(d)]
2. Room 345 in the Building 2 Blueprint Legend is not shown on the Building 2 Blueprint. [Reference: 9 CFR 108.4(e)]

Blueprint Legend, Building 1

pages 1-27

1. The function of Room 450 is not described in the Building 1 Blueprint Legend. [Reference: 9 CFR 108.5(b)(1)]
2. During the October 23, 2007, special inspection of the firm, they stated that they work with organisms in Rooms 246 and 124, Building 1; however, no fractions are listed for these rooms in the Building 1 Blueprint Legend. [Reference: 9 CFR 108.5(b)(1)]

Blueprint Legend, Building 2

pages 1-22

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Blueprint Legend, Building 1
Appendix 1,
Decontamination
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Cross Contamination
pages 1-2

The firm did not describe how they decontaminate rooms where licensed product is exposed to the environment. [Reference: 9 CFR 108.5(b)(1)]

Blueprint Legend, Building 1
Appendix 2, List of Fractions
pages 1-3

The firm did not include any of the select agents they use in the list of fractions. [Reference: 9 CFR 108.5(b)(1)]

Additional Comments:

1. The incorrect supersedes date was used for the plot plan, plot plan legend, Building 1 and Building 2 Blueprints, and the Building 2 Blueprint Legend. For future facility document revisions, the supersedes date used to identify what is being superseded is the date stamped within the blue "Filed with the USDA" box at the bottom of each page of the facility documents.

[Reference: 9 CFR 108.6(a)]

2. The responsible official did not sign the plot plan or blueprints.

[Reference: 9 CFR 108.3(h) and 108.4(k)]

3. Additional information for preparing facility documents can be found in 9 CFR 108, and Veterinary Services Memorandum 800.78. These documents are available on the CVB website at:

http://www.aphis.usda.gov/animal_health/vet_biologics/vb_regs_and_guidance.shtml.

If you have any questions regarding this matter, please contact me at (515) 337-6100.