

Before you submit:

1. A template letter has been prepared for you to use as you draft your letter.
2. All letters must include your name and the docket number, FDA-2014-D-1525. The template letter provided includes the docket number in the appropriate location.
3. You can visit a webpage devoted to the draft guidance at regulations.gov and search for the guidance's Federal Register Number, "FDA-2014-D-1525-0002."

The draft guidance's name is ["Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application."](#)

4. Once you've written your letter, you are ready to submit it.

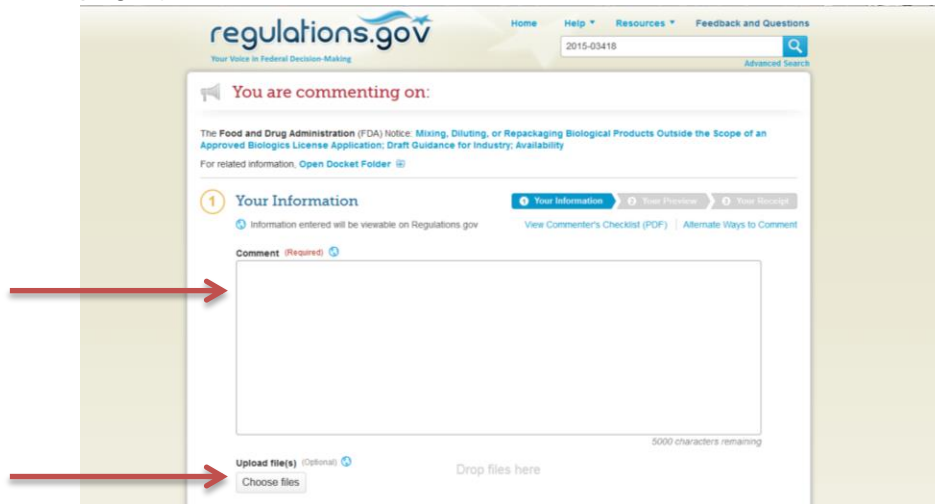
There are two ways to submit your letter:

✓ By Mail:

1. Address your letter to:
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
2. **Letters must be mailed by May 6, 2015** so that they reach the FDA in time.
3. Please also email your comment letter to ASRS Executive Vice President Jill Bill (jill.blim@asrs.org) us so that we can maintain our records.

✓ Online:

1. Follow this link to the correct submissions form: <http://1.usa.gov/1FBbuAL>
2. You can either
 - Cut and paste your letter into the comment box (note there is a 5,000 character limit, which is approximately 1.5 typed pages), or
 - Upload your letter by clicking "choose files" and following the instructions (there is no character limit for an uploaded letter, but we recommend your letter not exceed two typed pages).



The screenshot shows the 'regulations.gov' website interface. At the top, there's a navigation bar with 'Home', 'Help', 'Resources', and 'Feedback and Questions'. Below this, a search bar contains the text '2015-03418'. The main content area is titled 'You are commenting on:' and displays the draft guidance title: 'The Food and Drug Administration (FDA) Notice: Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application; Draft Guidance for Industry; Availability'. Below the title, there's a section for 'Your Information' with a progress indicator showing 'Your Information' as the first step. A 'Comment (Required)' text box is present, with a red arrow pointing to it. Below the text box, there's an 'Upload file(s)' section with a 'Choose files' button, also indicated by a red arrow. The text '5000 characters remaining' is visible at the bottom right of the comment box.

3. Scroll down the screen and provide your first and last name in the appropriate fields, check “I want to provide my contact information,” and fill out the online form when it appears. Deselect “I am submitting on behalf of a third party.”

5000 characters remaining

Upload file(s) (Optional) Drop files here

Choose files

First Name Last Name

☒ I want to provide my contact information

State or Province ZIP/Postal Code

Country

United States

Email Address

☐ I am submitting on behalf of a third party

4. Click on the “Category” drop down menu and scroll down to select “Health Professional – A0007”

☒ I am submitting on behalf of a third party

Category (Required)

Federal Government - G0007

Food Association - D0017

Food Industry - C0027

Government

Health Care Association - D0022

Health Professional - A0007

Individual Consumer

International Association - I0027

International Consumer Group - I0012

International Food Association

International Government - G0037

Continue

Submitting comment submission.

Information on this comment form or in an attachment may be publicly disclosed and searchable on the Internet. If you are submitting information to the Department or Agency issuing the notice. To view any additional information for the submissions, refer to the [Privacy Notice](#) and [User Notice](#), the Federal Register notice on the Department or Agency.

Resources

Help

Connect With

Site Data

How to use Regulations.gov

Regulatory Agenda

FAQs

Agency Reports Required by Statute

Glossary

Executive Order 12866

Executive Order 13563

Developers

Feedback and Questions

Privacy and Security Notice

User Notice

Accessibility Statement

5. Click on the blue “Continue” arrow in the bottom right hand corner
6. Verify that your information is correct.
 - Click the edit button if there is incorrect information.
7. Check the “I read and understand the statement above” and click “Submit Comment.”
8. A screen will appear with a confirmation number for your comment. Copy the number down as confirmation that your comments have been received.
9. **Letters must be submitted online by May 20, 2015.**
10. Please also email your comment letter to ASRS Executive Vice President Jill Bill (jill.blim@asrs.org) us so that we can maintain our records.