## Service of Legal Documents on the Food and Drug Administration

Email service is now the preferred means for service of process on the Food and Drug Administration (FDA) and any agency officials and employees who are being sued in their official capacity. Email service is also preferred for service of subpoenas.

## **Email Service of Complaints and Petitions for Review**

In addition to the means of service provided under Federal Rule of Civil Procedure 4(i)(2), FDA and its officers or employees sued in their official capacity may be served with civil summonses and complaints by email according to the following terms and conditions, which must be strictly adhered to if email service is attempted. Service of petitions for review of agency action in a court of appeals under Federal Rule of Appellate Procedure 15(c) are also accepted in accordance with these conditions. If service is performed consistent with the following provisions, the Government will not argue under Federal Rule of Civil Procedure 12(b)(5) that service on FDA or its officers or employees in their official capacity has not been accomplished.

- Service must be made at <u>OC-OCC-FDA-Litigation-Mailbox@fda.hhs.gov</u> and no other email address.
- The subject of the email must contain the caption of the suit with the court-assigned docket number, e.g., "Company v. FDA, 23-9999 (D.D.C.)"
- The summons, complaint, and all exhibits or other documents must be combined into a single PDF, with the summons coming first in the PDF, unless the file size of the combined PDF exceeds 20 megabytes.
- Service packages exceeding 20 megabytes must be broken into PDF files of no more than 20 megabytes and sent using separate emails with a notation in the subject that it is multi-part service, e.g., "Company v. FDA, 22-9999 (D.D.C.) (Email 1 of 2)."
- If you are serving a copy of a motion for a preliminary injunction or temporary restraining order with your summons and complaint, you should also include that in the email. This may be a separate document.
- You must receive an autogenerated message indicating that your email has been received.

The email address OC-OCC-FDA-Litigation-Mailbox@fda.hhs.gov should not be used for any other communications with FDA aside from civil service of process described above. Other communications sent to that address will not be considered. FDA is not authorized to accept service on behalf of the U.S. Attorney's Office, the Attorney General, or any other government defendant. Thus, if an applicable rule requires any such entities and persons to be served, they must be served separately and in addition to service upon FDA and its officers and employees.

## <u>Certified/Registered Mail Service of Complaints and Petitions for Review</u>

In the alternative, service of complaints and summonses on the Food and Drug Administration may be made in compliance with Rule 4(i) of the Federal Rules of Civil Procedure through registered or certified mail. Mail may be addressed to:

- Chief Counsel, Food and Drug Administration
- ATTENTION: LITIGATION
- White Oak Building 31, Room 4544
- 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

Similarly, service of petitions for review of agency action in a court of appeals may be sent to the address above.\*

## **Email Service of Subpoenas**

Email service of subpoenas on the Food and Drug Administration under Rule 45 of the Federal Rules of Civil Procedure is also preferred and is currently accepted on business days between 9 am -5 pm ET at this email address:

OCOCCFDASubpoenaServiceMailbox@fda.hhs.gov. Email service outside those business hours will be accepted on the next business day. For service to be complete, you must receive an autogenerated message indicating that your email has been received.

\*The addressee information in 21 C.F.R. § 10.45(h)(1) is outdated.