



### FDA Records Request

Requesting Office Street Address	City	State	Zip Code
To: Name of Individual	Title of Individual		Date of Request
Firm Name			
Firm Street Address	City	State	Zip Code
Country			

**Under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)(4)], FDA requests that you provide the records described below. If the records requested do not exist, please state that fact in your response.**

#### DESCRIPTION OF RECORDS REQUESTED

FDA is requesting the records and/or other information identified above to:

- Prepare for an inspection
- Collect in advance of an establishment's voluntary participation for scheduled Remote Interactive Evaluation
- Follow-up to \_\_\_\_\_
- Assist with the review of the marketing submission for \_\_\_\_\_
- Verify whether your establishment, site, or facility has corrected deficiencies observed during \_\_\_\_\_
- Collect information about \_\_\_\_\_
- Other (specify): \_\_\_\_\_

Please submit the above-described records by email to the contact email below by **(Date)** \_\_\_\_\_. If you are unable to send via email and would rather send via mail, please contact the FDA contact email below.

If the primary language of the records requested is one other than English, please also provide an English translation of the records verified to be complete and accurate, together with the name, address, and a brief statement of the qualifications of the person making the translation along with copies of the original records.

If you have any questions or concerns regarding your ability to respond to this request by the specified date, please contact the FDA contact named below.

Failure to submit the requested records by the date requested may cause your product to be adulterated within the meaning of section 501(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 351(j)].

See attachment for any additional records requested.

FDA Contact Email	FDA Contact Phone Number
Typed Name and Title of FDA Contact	Signature of FDA Contact