

**Public Health Service**

**MATERIAL TRANSFER AGREEMENT**

This Material Transfer Agreement (“MTA”) has been adopted for use by the National Institutes of Health, the Food and Drug Administration and the Centers for Disease Control and Prevention collectively referred to herein as the Public Health Service (“PHS”) in all transfers of research material (“Research Material”) whether PHS is identified below as its Provider or Recipient.

Provider:

Recipient: **FDA, Division of Pharmaceutical Analysis**

1. Provider agrees to transfer to Recipient’s Investigator named below the following Research Material:

**Two (2) gram samples of multiple lots (at least 3 lots) of excipients with Certificate of Analysis for the lot. Material should be representative of the potential spectral variability that might be expected in their product. Samples should be labeled with the following information where applicable:**

- **Name of Manufacturer**
- **Manufacture site**
- **Excipient Name**
- **Trade name**
- **Compendial or excipient grade**
- **Lot designation**
- **Date of Manufacture**
- **Special handling or packaging requirements**

**Samples should conform to market standards and/or standards filed with the agency.**

**2. THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS.**

This Research Material will only be used for research purposes by Recipient’s investigator in his/her laboratory, for the Research Project described below under suitable containment conditions. This Research Material will not be used for commercial purposes such as serving, production or sale, for which a commercialization license may be required. Recipient agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.

2(a). Are Research Materials of human origin? \_\_\_\_\_yes\_\_\_\_\_ **X**\_\_\_\_\_no

2(b). If yes in 2(a), were Research Materials collected according to 45 CFR 46 “Protection of Human Subjects?” \_\_\_\_\_yes\_\_\_\_\_no

Please provide Assurance Number: \_\_\_\_\_

3. This Research Material will be used by Recipient's investigator solely in connection with the following research project ("Research Project") described with specificity as follows (use an attachment page if necessary):

**Excipient samples will be analyzed with portable analyzers located at the Division of Pharmaceutical Analysis. The analyzer may include Raman spectrometers, NIR spectrometers, X-ray fluorescence spectrometers and ion mobility spectrometers. Spectra will be stored in spectral libraries for the purpose of establishing criteria by which excipients from specific manufacturers can be authenticated. In some cases, reference methods such as inductively coupled plasma mass spectrometry and high performance liquid chromatography may be employed to verify the results of the spectral measurements performed with portable analyzers.**

4. In all oral presentations or written publication concerning the Research Project, Recipient will notify the Provider 30 days in advance to allow review as well as acknowledge Provider's contribution of this Research Material unless requested otherwise. To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of Provider's written information about this.

Research Material that is stamped "**CONFIDENTIAL**," except for information that was previously known to Recipient or that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Recipient may publish or otherwise publicly disclose the results of the Research Project, but if Provider has given CONFIDENTIAL information to Recipient such public disclosure may be made only after Provider has had thirty (30) days to review the proposed disclosure, except when shortened time period under court order or the Freedom of Information Act pertains.

5. This Research Material represents a significant investment on the part of Provider, and is considered proprietary to Provider. Recipient's investigator therefore agrees to retain control over this Research Material, and further agrees not to transfer the Research material to other people not under her or his direct supervision without advance written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. When the Research Project is completed, or three (3) years have elapsed, whichever occurs first, the Research Material will be destroyed by Recipient or otherwise disposed of as mutually agreed by Provider and Recipient.

6. This Research Material is provided as a service to the research community. **IT IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.

7. **When Provider is the PHS:** Recipient shall retain title to any patent or other

intellectual property rights in inventions made by its employees in the course of the Research Project. Recipient agrees not to claim, infer, or imply Governmental endorsement of the Research Project, the institution or personnel conducting the Research Project or any resulting commercial product (s). Unless prohibited by law from doing so, Recipient agrees to hold the United States Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of Recipient's use for any purpose of the Research Material.

8. **When Recipient is the PHS:** The PHS shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. The PHS is not authorized to promise rights in advance for inventions developed under this Agreement. Provider acquires no intellectual property rights under this MTA, but may apply for license rights to any patentable invention that might result from this Research Project. It is the intention of PHS that Provider not be liable to PHS for any claims or damages arising from PHS's use of the Research Material; however, no indemnification is provided or intended.

9. The undersigned Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

10. This MTA shall be construed in accordance with Federal law as applied by Federal courts in the District of Columbia.

Date: \_\_\_\_\_  
Recipient's Investigator and Title

Date: \_\_\_\_\_  
Authorized Signature for Recipient and Title

Recipient's mailing address: **FDA**  
**1114 Market Street**  
**Room 1002**  
**St. Louis, MO 63101**

Date: \_\_\_\_\_  
Provider's Investigator and Title

Date: \_\_\_\_\_  
Authorized signature for Provider and Title

Provider's mailing address: \_\_\_\_\_



<b>Excipient</b>	<b>Initial or mark if provided</b>
BUTYLATED HYDROXYANISOLE	
BUTYLATED HYDROXYTOLUENE	
CALCIUM PHOSPHATE (DIBASIC)	
CALCIUM STEARATE	
CARBOXYMETHYL CELLULOSE	
CASTOR OIL	
CRESOL	
CROSCARMELLOSE	
CROSPVIDONE	
ETHYLCELLULOSE	
GELATIN	
Glycerin	
HYDROXY PROPYL CELLULOSE	
HYDROXY PROPYL METHYLCELLULOSE	
LACTOSE	
MAGNESIUM STEARATE	
MALTODEXTRIN	
MICROCRYSTALLINE CELLULOSE	
Polyethylene Glycol, liquid	
Polyethylene Glycol, solid	
POLYSORBATE 80	
POVIDONE	
PREGELATINIZED STARCH	
Propylene Glycol	
SHELLAC	
SILICON DIOXIDE	
SODIUM STARCH GLYCOLATE	
Sorbitol	
STARCH (CORN)	
STEARIC ACID	
SUCROSE	
TALC	
TITANIUM DIOXIDE	
Other (specify):	