

**Nomination and Approval of CBER Inspectors and Product Specialists Assigned to  
Conduct Inspections of Biological Products  
SOPP 8505**

**APPENDIX 1**

Instructions for completing FDA Form 2115, Credential Record Form

<b>Item No.</b>	<b>Completion Instructions:</b>
1 through 8	Fill out the personal information for the person to whom the credentials will be issued.
9 and 10	Check appropriate box
11	Justification – The justification statement should be modeled after the following example: <i>“This individual is regulatory and routinely participates in the conduct of inspections under the Public Health Service Act and the Federal Food, Drug and Cosmetic Act as [a Product Specialist or an Inspector] and requires credentials.”</i>
12	Director, OCBQ signature block
13	Authorizing official, HFC-132, signature block The authorizing official is a representative of the Division of Emergency and Inspectional Operations (DEIO). Their offices are in the Parklawn Building, Room 1371. Phone: 301/827-5653
14	<b>Do not sign until inspection credentials are issued</b>