

[Company]

List A--Putative AG Drugs

Question 4

	A	B	C
1	Brand-Name Drug with Putative AG	Active ingredient	AG? (Yes/No)

[Company]

List B--Brand-Name Drugs Subject to Paragraph IV Certifications

Question 5

	A	B	C	D	E	F
1	Brand-Name of Drug Subject to ¶ 4	Active Ingredient	Dosage Form	NDA #	Dosage Strength	AG? (Yes/No)

	A	B	C	D	E	F	G	H	I	J
1	AG Trade Name, if any	Brand-Name	Active Ingredient	Dosage Form	NDA #	Dosage Strength	NDA Date of Approval (for each strength)	AG - 9 digit NDC # (Labeler Code - Product Code)	NDC Date of Launch	NDC Date of Discontinuance, if any

	H	K	L	M	N	O	P	Q
1	AG - 9 digit NDC # (Labeler Code - Product Code)	AG Labeler/Entity Name	AG Labeler/Entity Relationship to Company	AG Labeler/ Marketing Entity Address & Phone	<u>QUESTION 7</u> Coordinate with marketing entity? (Yes/No)	STOP!! FILL IN COLUMNS P & Q WITH PART III.	<u>QUESTION 10</u> Date of first announcement of AG marketing	<u>QUESTION 11</u> Settlement agreement related to AG marketing? (Yes/No)

	A	B	C	D	E	F	G	H	I	J
1	Brand-Name (AG version marketed)	Active Ingredient	Dosage Form	NDA #	Dosage Strength	NDA Approval Date (for each strength)	9 digit NDC # (Labeler Code - Product Code)	Labeler/Entity Name	Labeler/Entity Relationship to Company	Therapeutic Category

	A	K	L	M	N	O	P	Q	R
1	Brand-Name (AG version marketed)	Pharmacological Class	14-Digit Generic Product Identifier	Date of first ANDA-generic entry (or "none")	Generic entry via 180 day exclusivity? (Yes/No)	Name of ANDA- Generic Company #1 During Exclusivity	Name of ANDA- Generic Company #2 During Exclusivity	Name of ANDA- Generic Company #3 During Exclusivity	Enter columns for additional companies here ►►

	A	B	C	D	E	F	G	H	I
	Brand-Name (¶ IV- no AG marketed)	Active Ingredient	Dosage Form	NDA #	Dosage Strength	NDA Approval Date (for each strength)	9 digit NDC # (Labeler Code - Product Code)	Labeler/Entity Name	Labeler/Entity Relationship to Company
1									

	A	J	K	L	M	N	O	P	Q	R	S
1	Brand-Name (§ IV- no AG marketed)	Therapeutic Category	Pharma- cological Class	14-Digit Generic Product Identifier	Date of first ANDA- generic entry (or "none")	Generic entry via 180- day exclusivity? (Yes/No)	Name of ANDA- Generic Company #1 During Exclusivity	Name of ANDA- Generic Company #2 During Exclusivity	Name of ANDA- Generic Company #3 During Exclusivity	Enter columns for additional companies here ▶▶	Question 14 AG NOT Marketed Per Settlement Agreement (Yes/NO)