

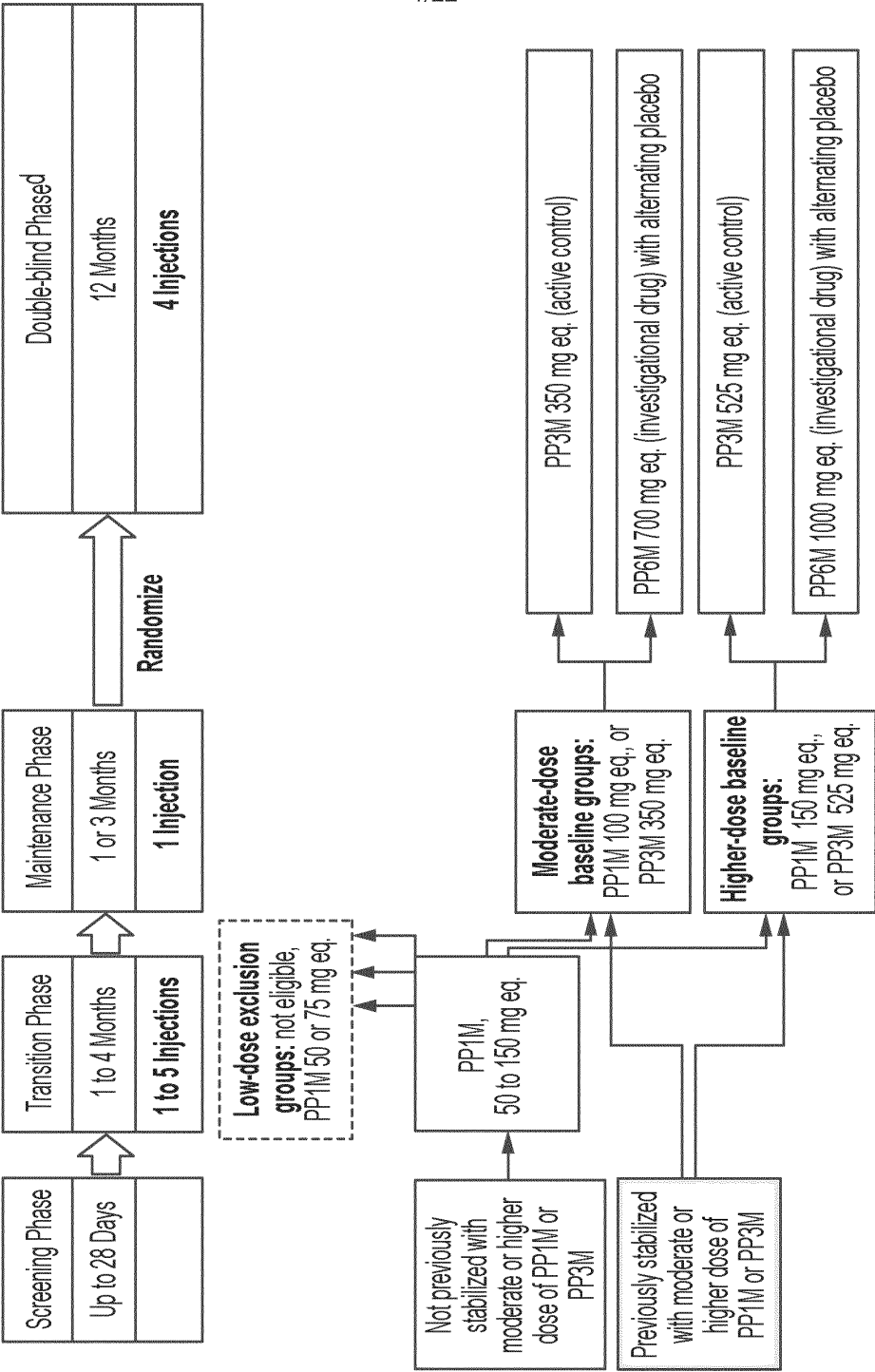


FIG. 1

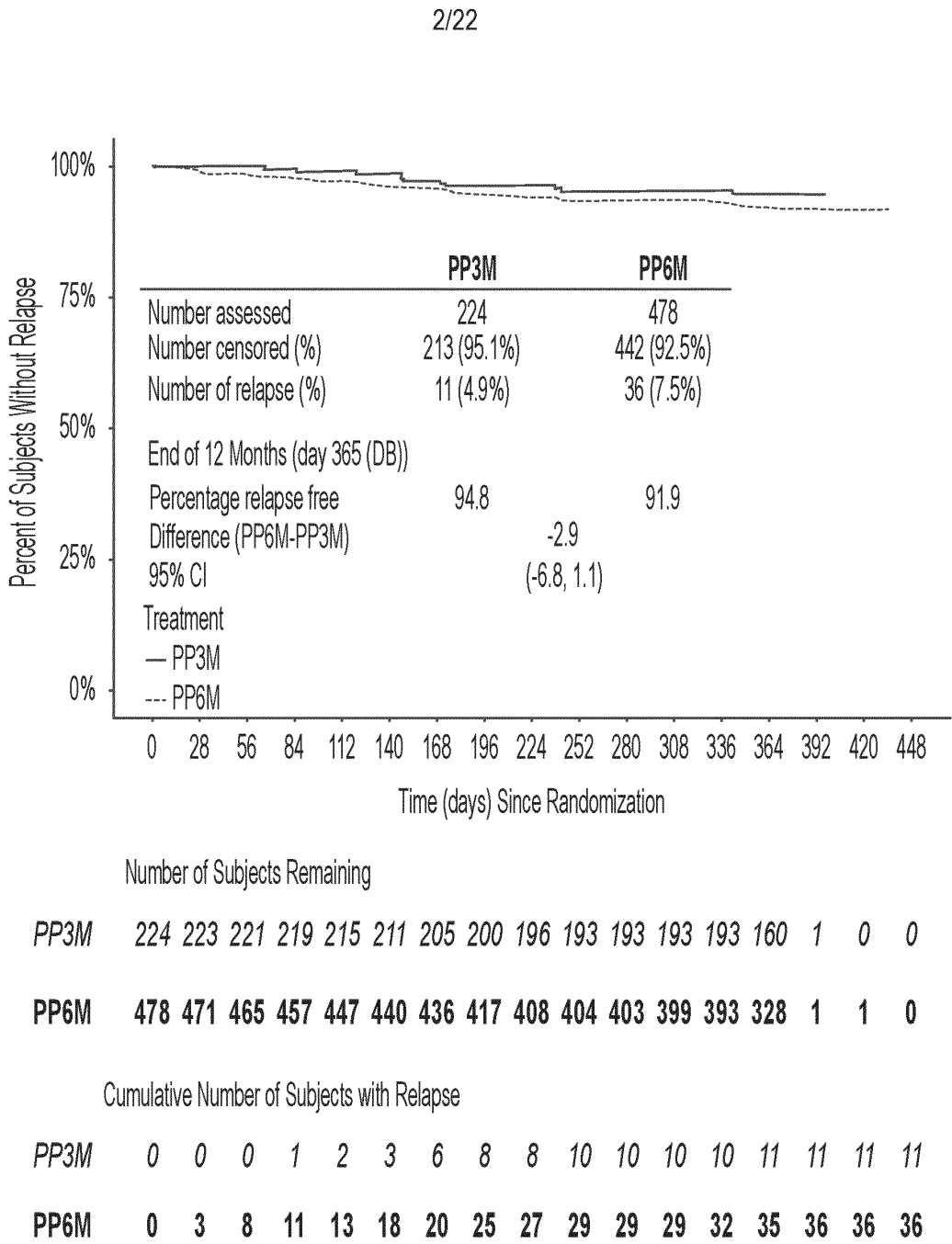


FIG. 2

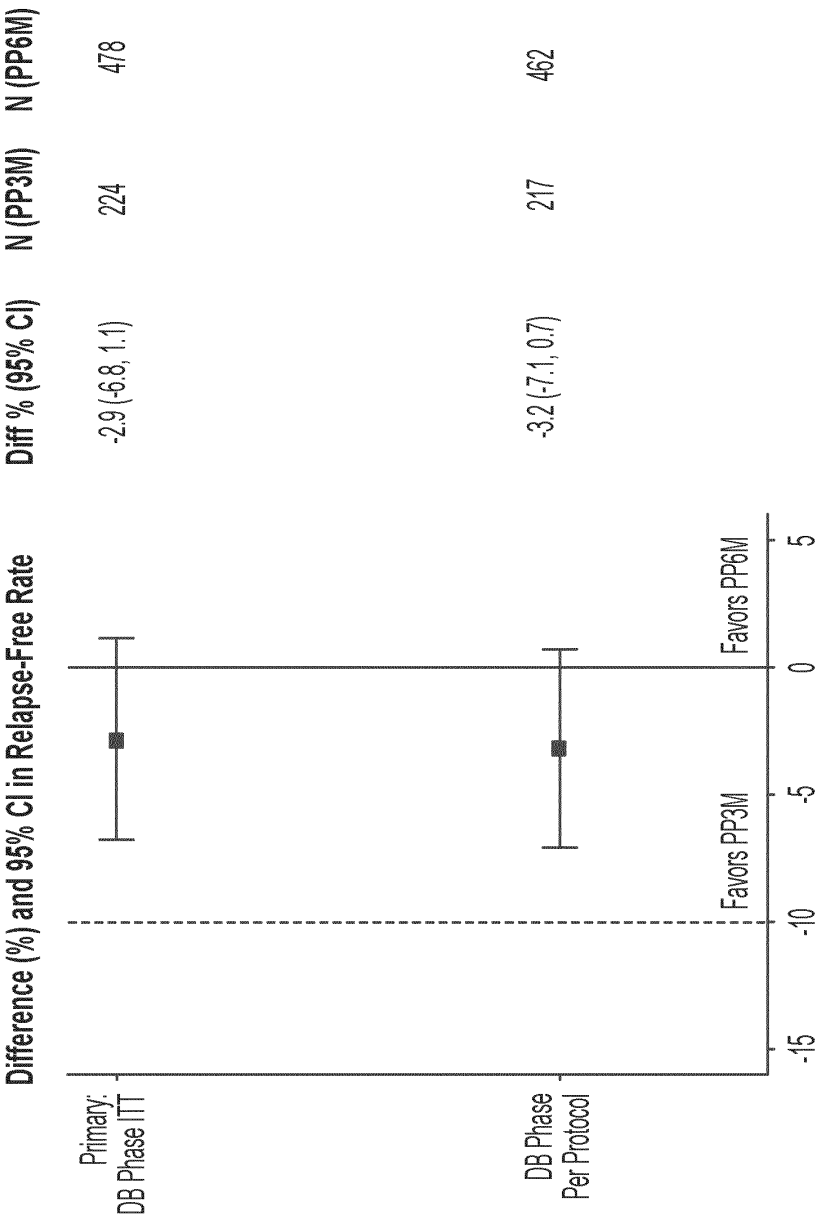


FIG. 3

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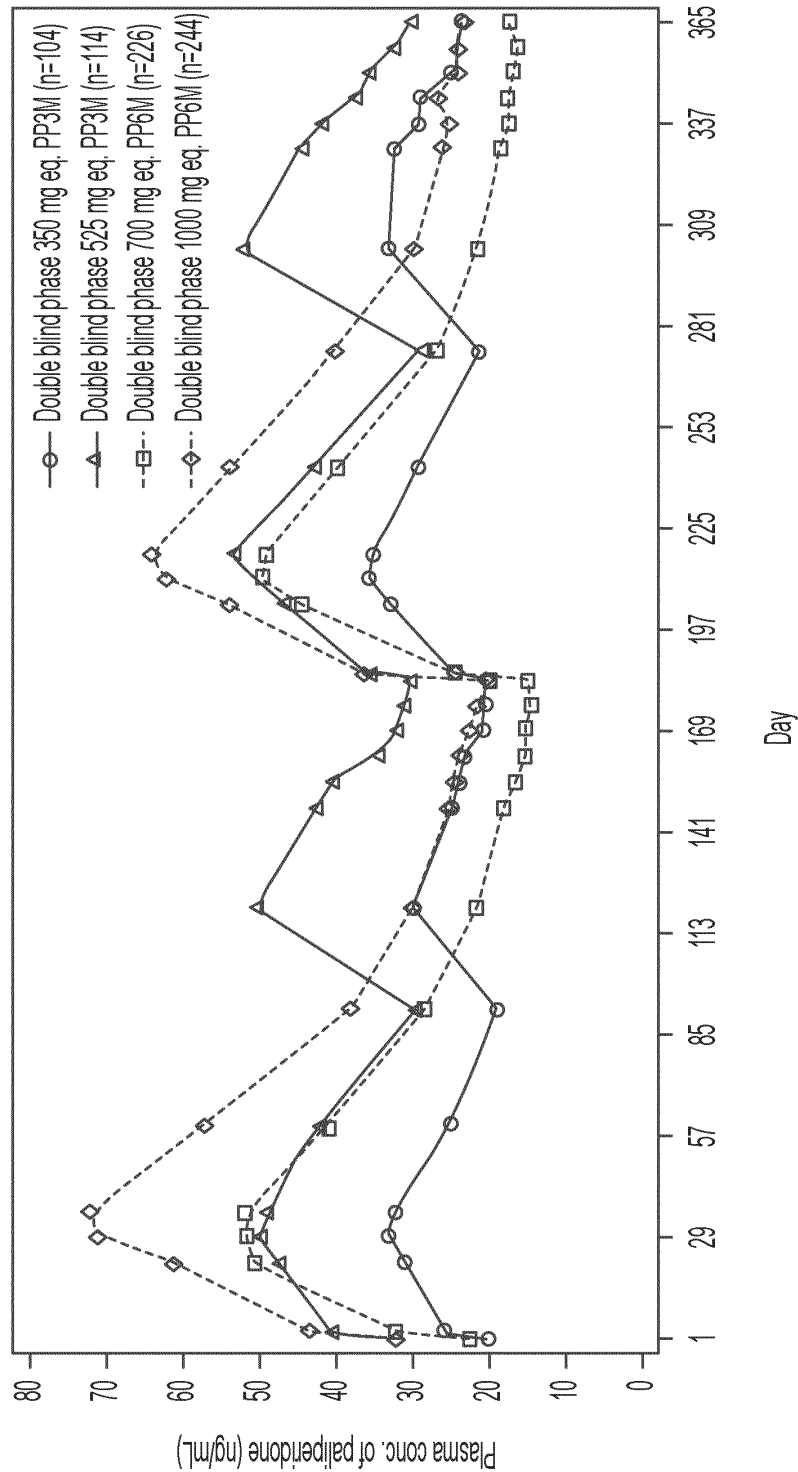


FIG. 4

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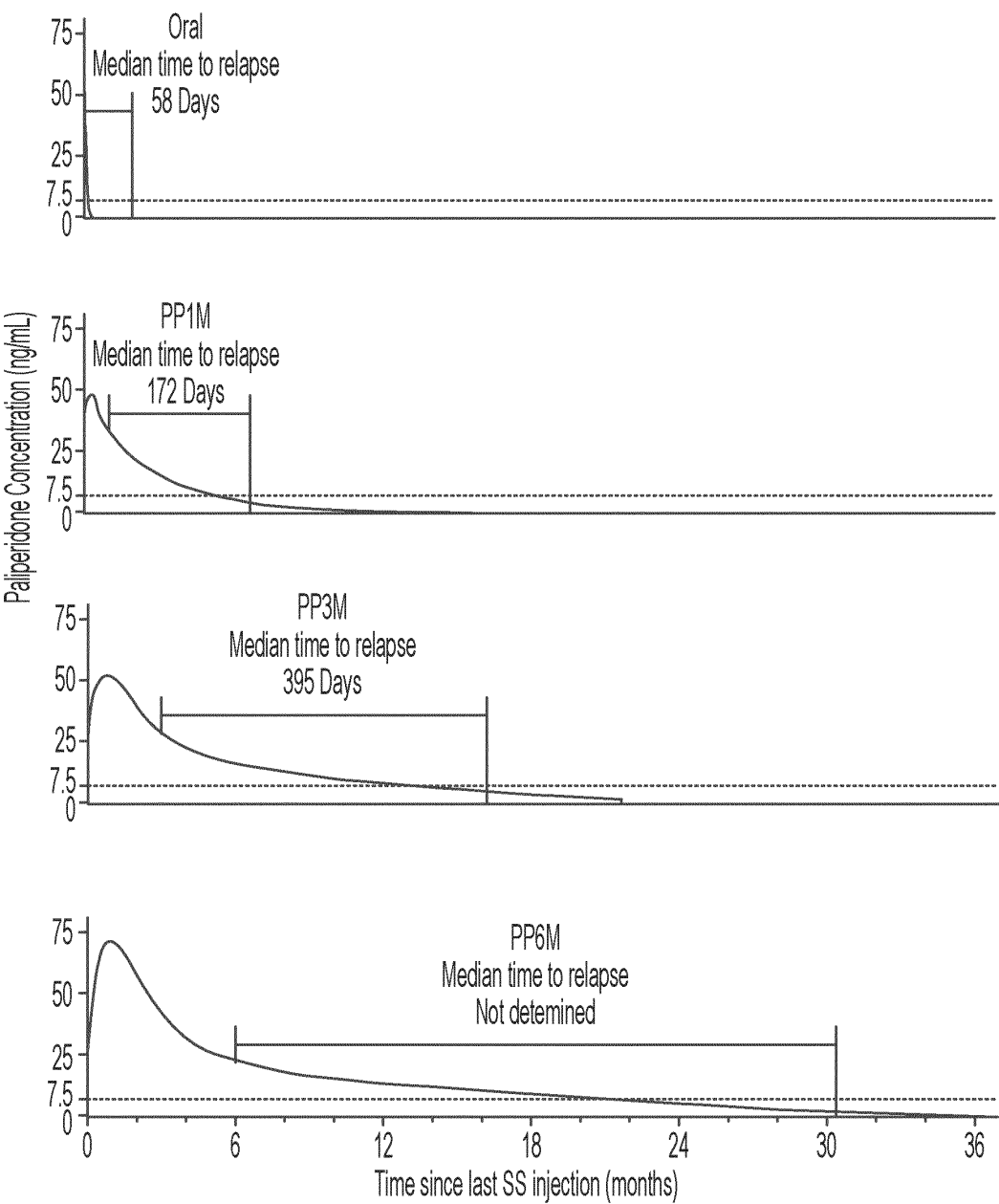


FIG. 5

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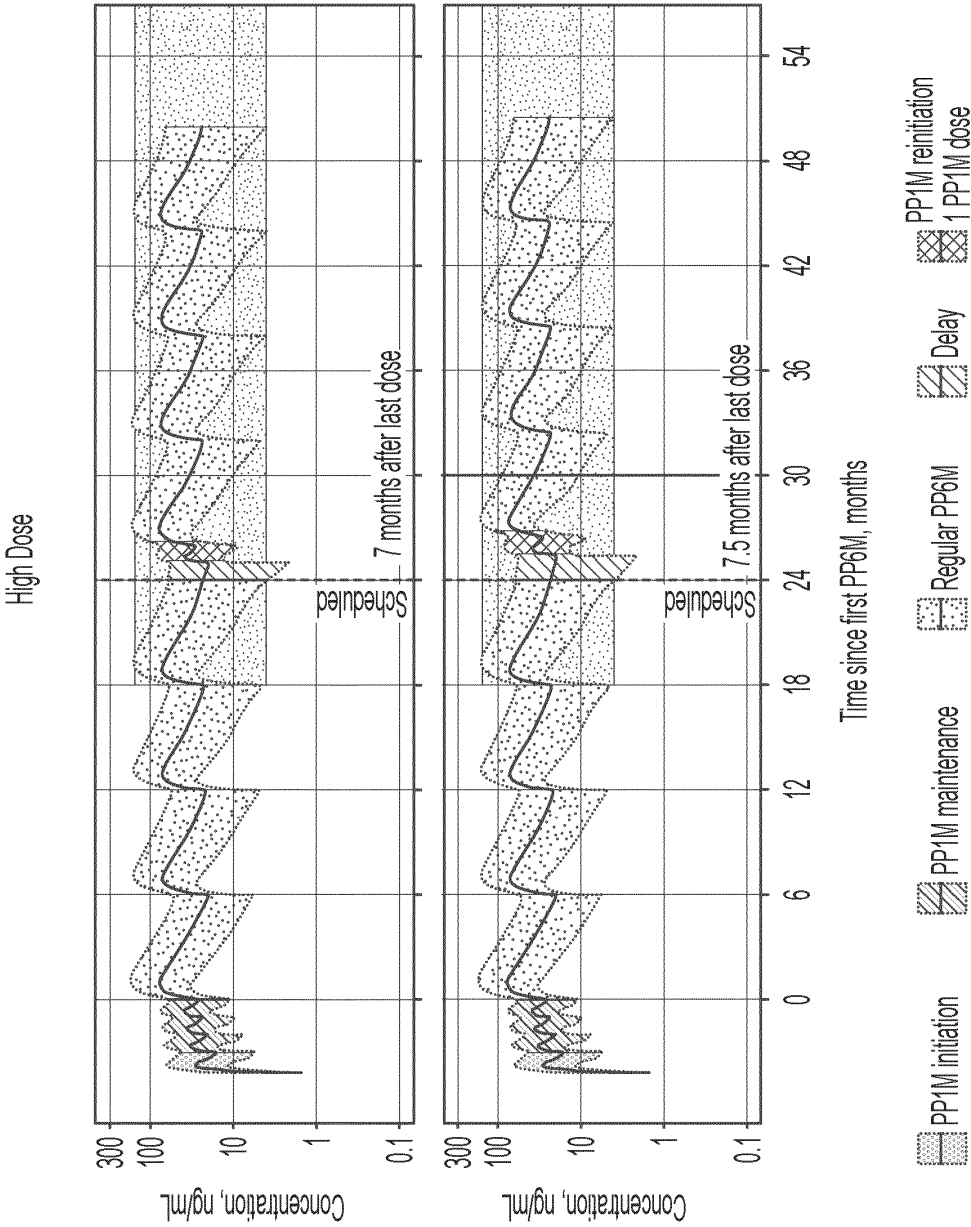


FIG. 6

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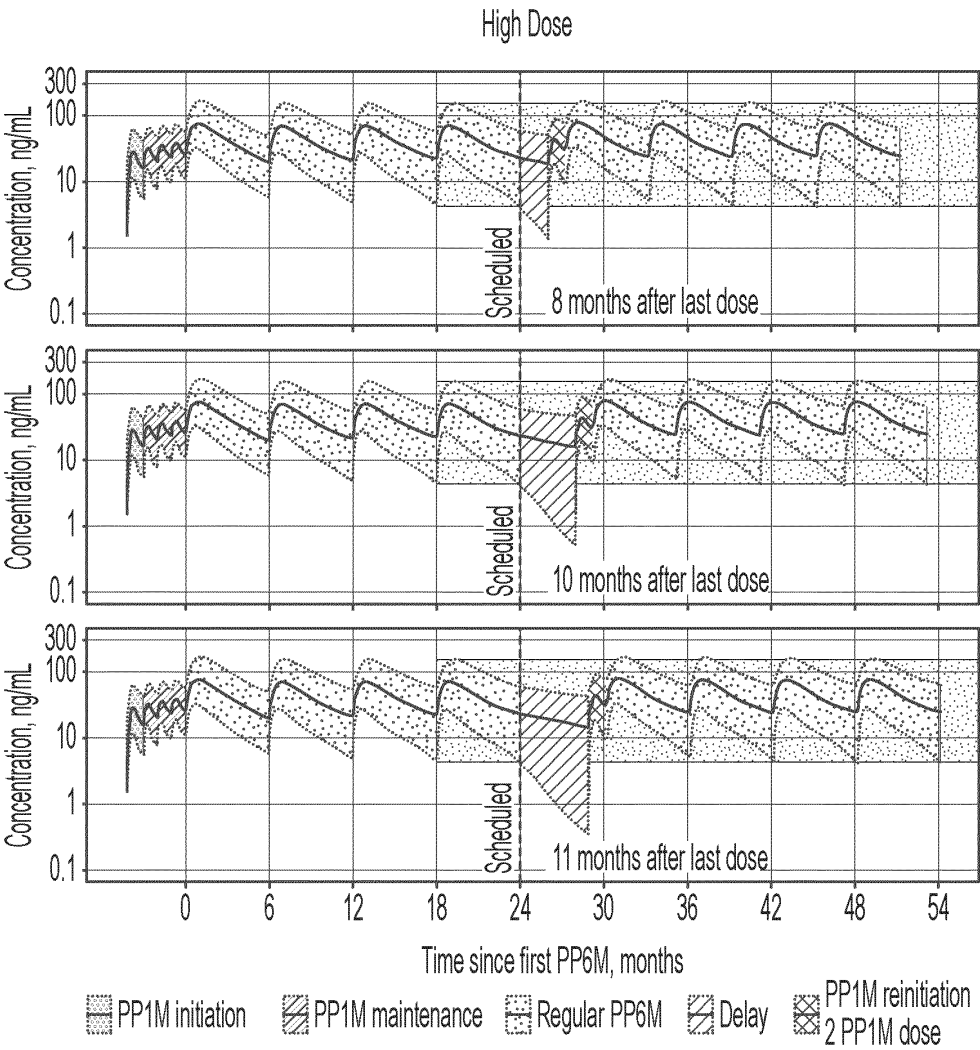


FIG. 7

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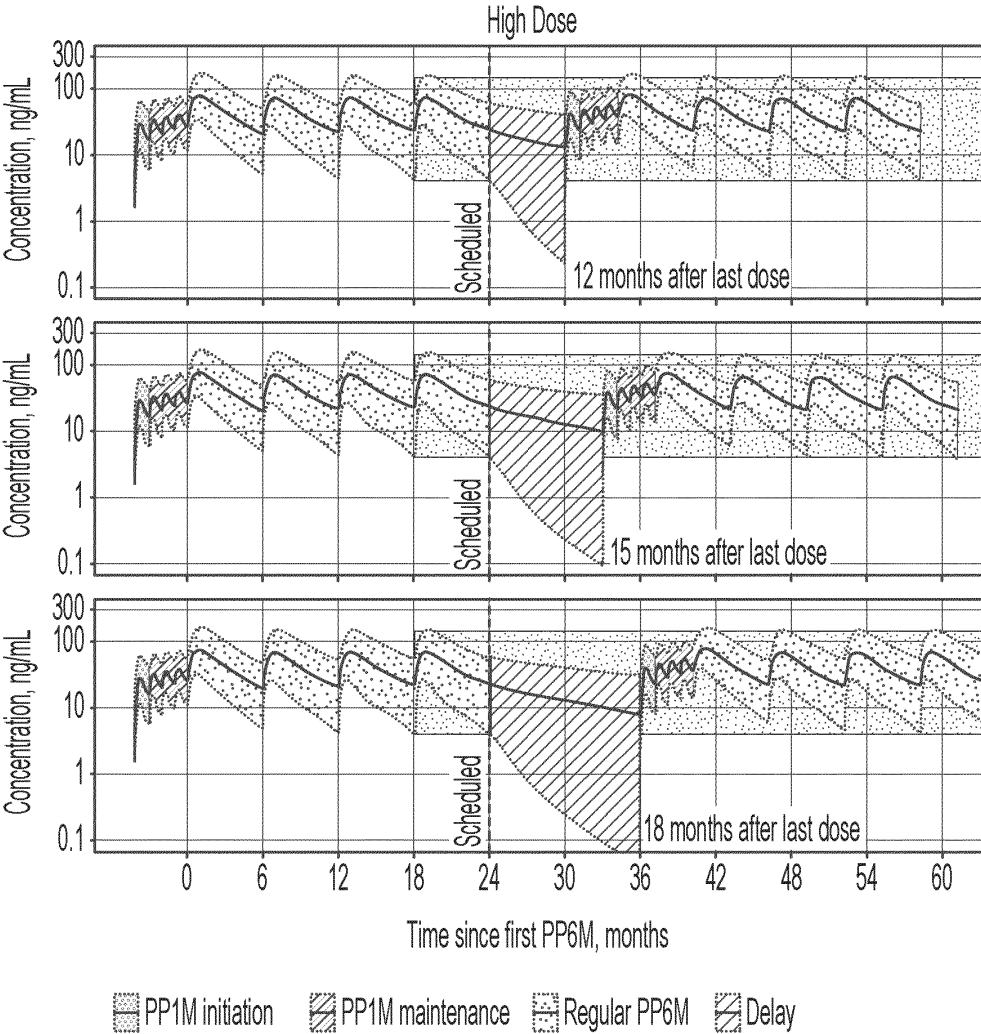


FIG. 8

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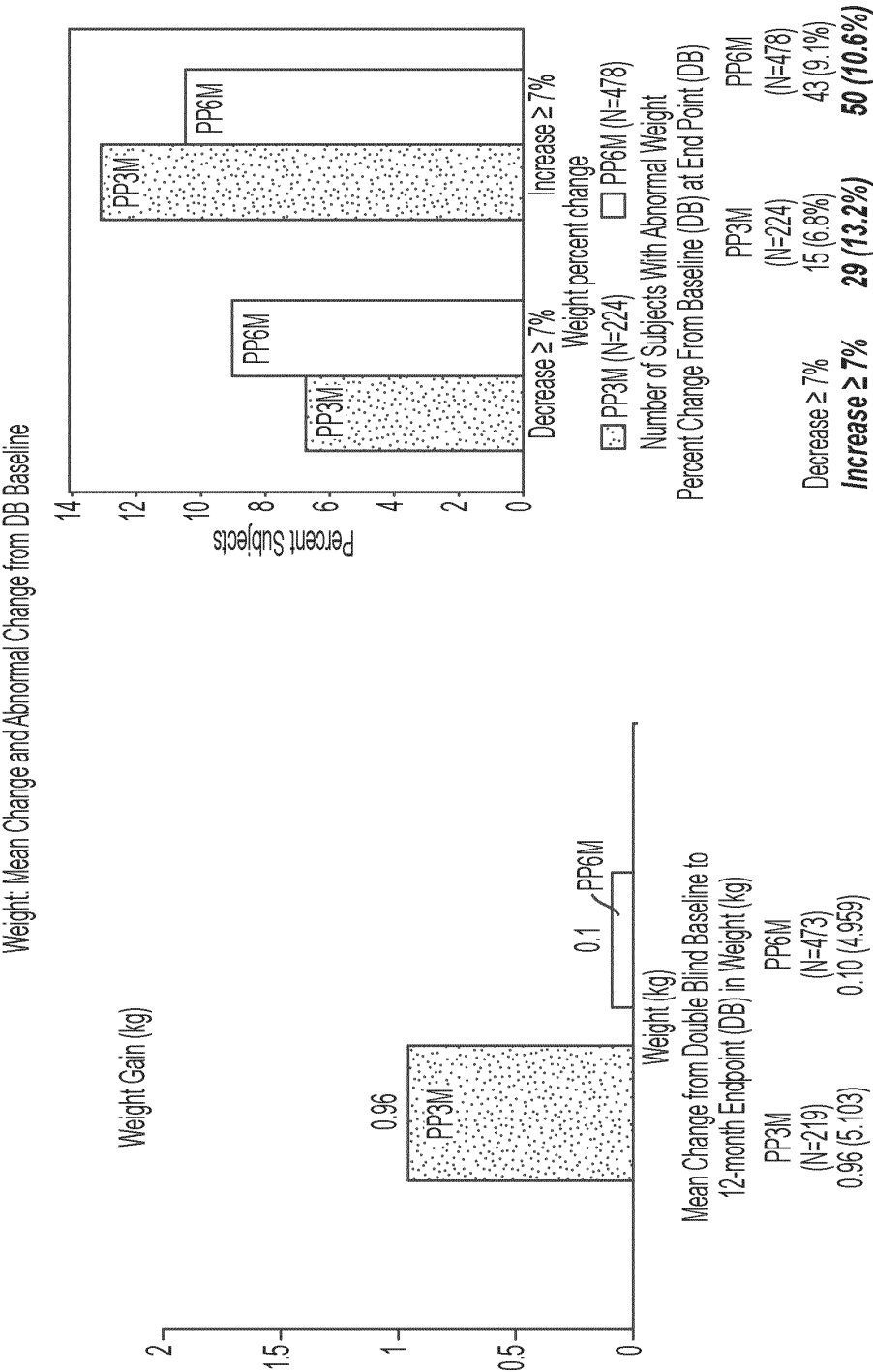


FIG. 9

10/22

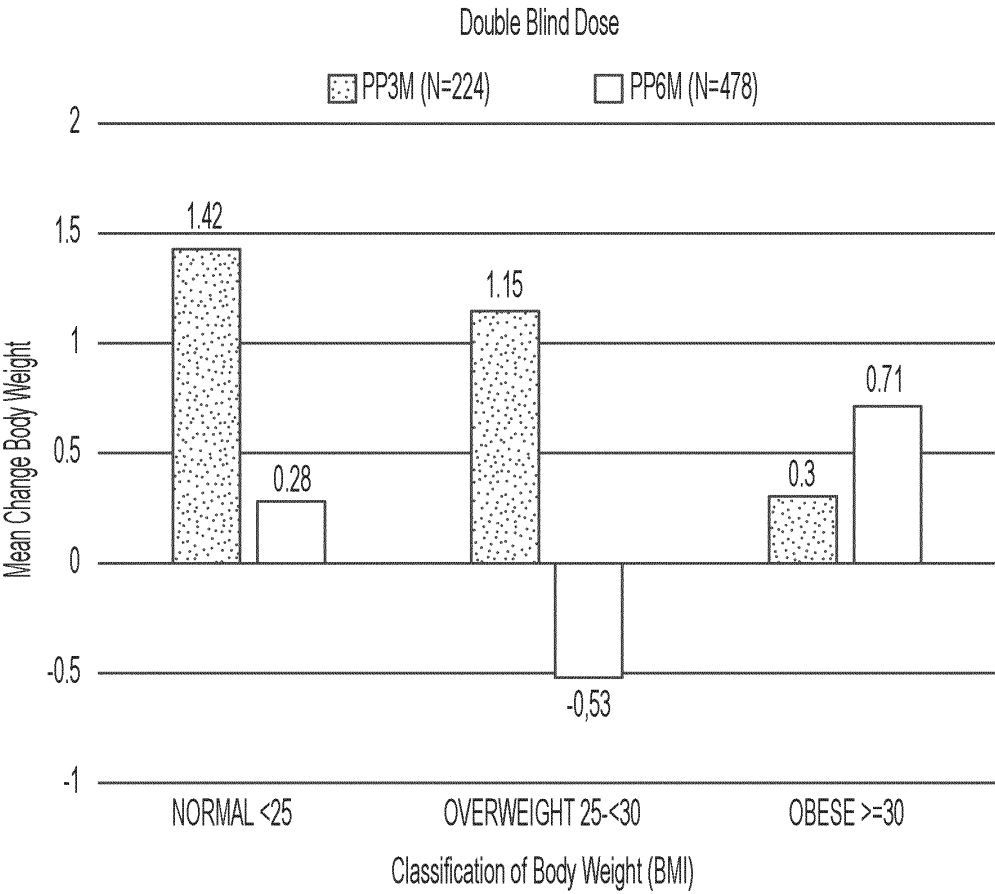


FIG. 10

11/22

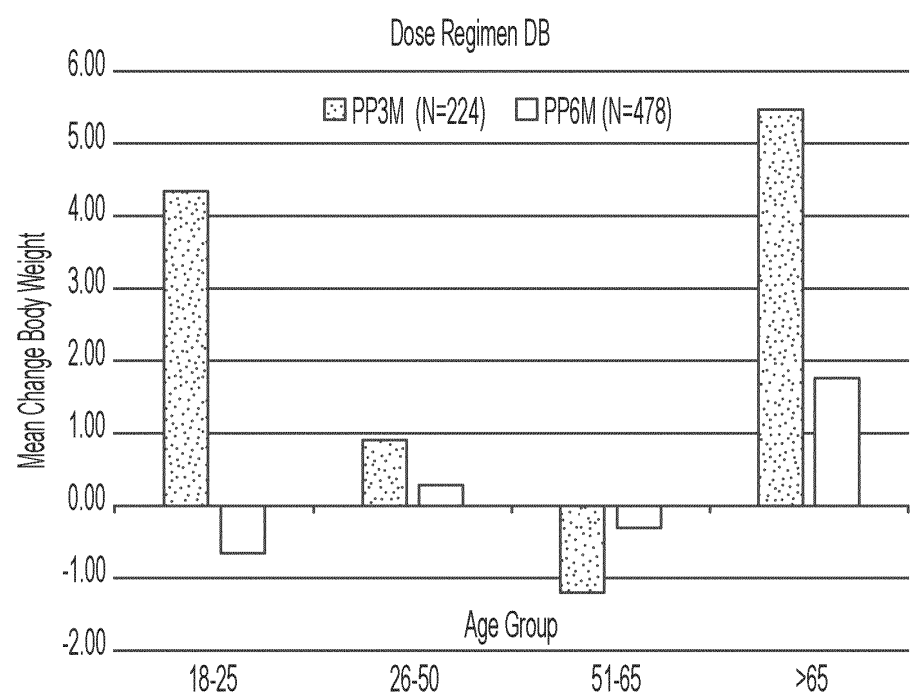


FIG. 11

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FIGURE 12A

INSTRUCTIONS FOR USE**INVEGA HAFYERA™**

In-VAY-guh HAF-ye-RA
(paliperidone palmitate)
extended-release injectable
suspension
For Gluteal Intramuscular
Injection Only

Administer every 6 months



Shake syringe with
the syringe tip cap
pointing up **VERY FAST**
for at least 15 seconds,
rest briefly, then shake
again for 15 seconds

**INSTRUCTIONS FOR USE****INVEGA HAFYERA™**

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(paliperidone palmitate)
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Administer every 6 months



Shake syringe with
the syringe tip cap
pointing up **VERY FAST**
for at least 15 seconds,
rest briefly, then shake
again for 15 seconds

Important

⚠ Shipping and storing the
carton in a horizontal orientation
improves the ability to resuspend
this highly concentrated product.

Preparation

INVEGA HAFYERA requires longer
and faster shaking than
once-a-month paliperidone
palmitate extended-release
injectable suspension
(e.g., INVEGA SUSTENNA).

INVEGA HAFYERA must be
administered by a healthcare
professional as a single injection.
Do not divide dose into multiple
injections.

INVEGA HAFYERA is intended for
gluteal intramuscular use only.
Inject slowly, deep into the muscle
taking care to avoid injection into
a blood vessel.

Dosing

Administer INVEGA HAFYERA once
every 6 months.

Thin Wall Safety Needle

Thin wall safety needle is designed
to be used with INVEGA HAFYERA.
Therefore, it is important to
only use the needle provided in the
INVEGA HAFYERA suspension kit.

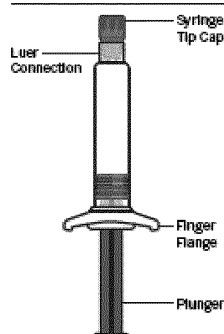
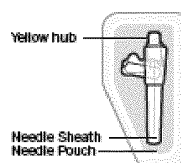
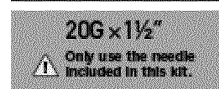
Dose pack contents**Prefilled Syringe****Thin Wall Safety Needle**

FIGURE 12B

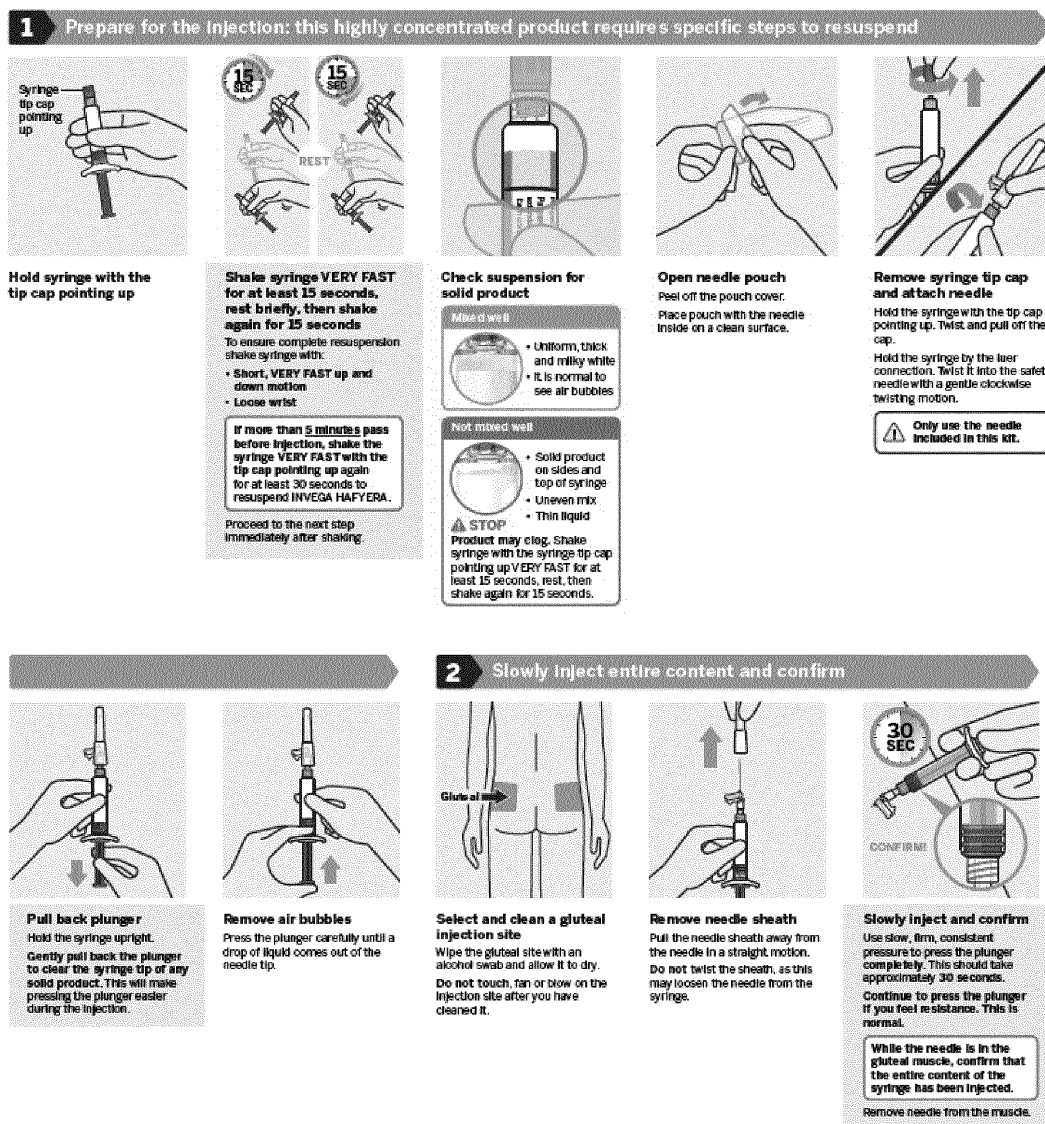
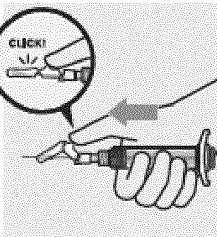


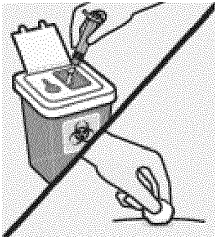
FIGURE 12C

3

After the Injection



Secure needle
After the injection is complete, use your thumb or a flat surface to secure the needle in the safety device.
The needle is secure when you hear a "click" sound.



Dispose of properly and check injection site
Dispose of the syringe in an approved sharps container.
There may be a small amount of blood or liquid at the injection site. Hold pressure over the skin with a cotton ball or gauze pad until any bleeding stops.
Do not rub the injection site.
If needed, cover injection site with a bandage.

This instructions for Use has been approved by the U.S. Food and Drug Administration.
Manufactured for:
Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560
Revised Aug 2021
© 2021 Janssen
Pharmaceutical Companies

Product Artwork CoE

janssen

Shared mailbox: RA-JANBE-GRAPHDES@its.jnj.com

Insert

INVEGA HAFYERA

PCC

728058

Template Ref. Name:

841178/V2
476x382 (folded 68x98)

Tech. info/Spec:

NA

Market:

USA

Mat. ID Code:

804

File Name:

728058.indd (CC)

Font Type:

Benton Sans

Font Size:

10 pt

Times New Roman compared to our standard fonts					
X-height (baseline) Times NR	Times New Roman	Helvetica World	Antique Olive	Futura	Karlon
100% max	9 pt	9 pt	8 pt	9.5 pt	9.2 pt
1.184 max	9 pt	9 pt	8.5 pt	9.7 pt	9.2 pt
1.262 max	9 pt	9 pt	8.8 pt	9.7 pt	9.2 pt
1.42 min	9 pt	9 pt	8.5 pt	9.5 pt	9.2 pt

■ Black

■ Cyan

■ Magenta

■ Yellow

Date

[Designer]

1.27-AUG-21 (Synd)

2.27-AUG-21 (Synd)

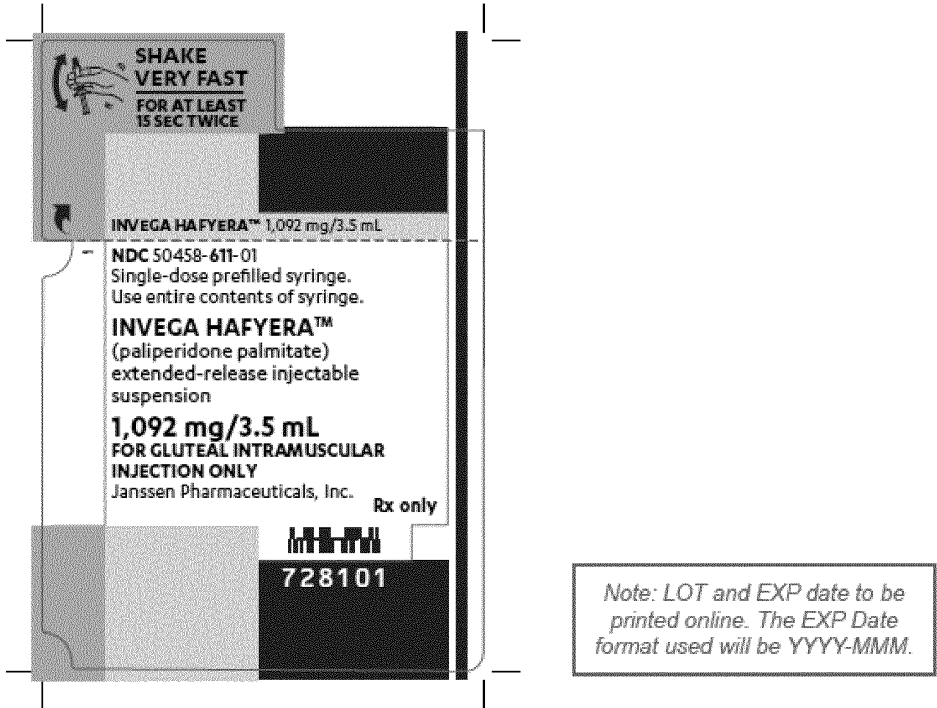
3.30-AUG-21 (Soumen)

4.

5.

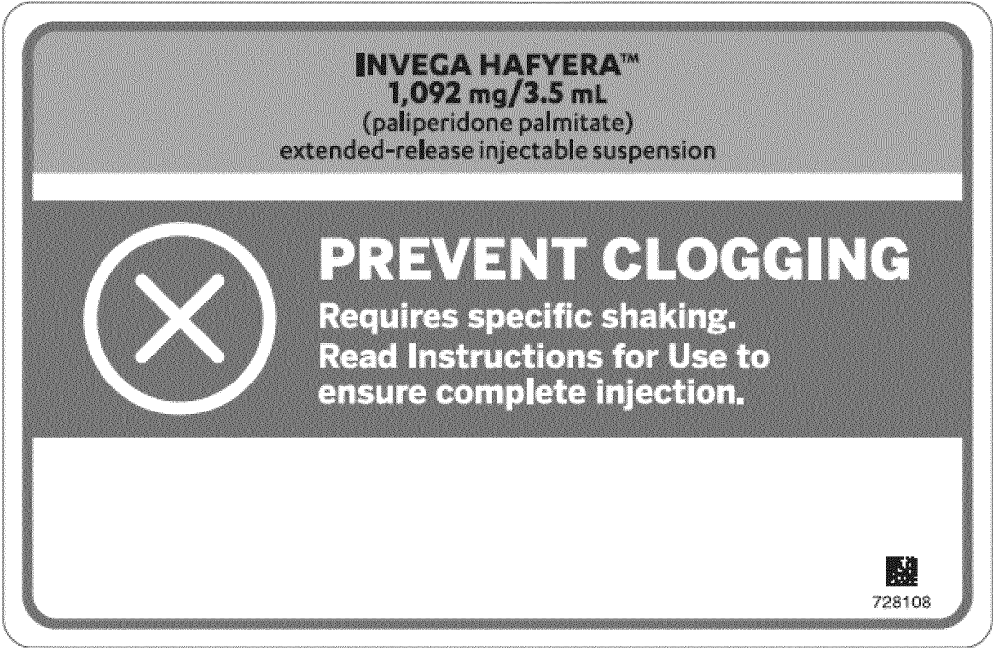
6.

FIGURE 13A



Label INVEGA HAFYERA PCC: 728101		Product Artwork CoE janssen 	
Template Ref. Name: B/L/305/US/V1 49x70 Tech. info/Spec: N/A Market: USA Mat. ID Code: PCC File Name: 728101.ai (CC-PC)		Shared mailbox: RA-JANBE-GRAPHDES@its.jnj.com	
		 Black	Date (Designer)
		 Black 2 + Microprint (459117)	1. 08-JUN-21 (Santosh)
		 Diecut (not to be printed)	2. 06-AUG-21 (Santosh)
		 PMS 915	3. 23-AUG-21 (Luis)
		 PMS 9464	4.
			5.
			6.
			7.
			8.
			9.
			10.
			11.
			12.
			13.

FIGURE 13B



Label

INVEGA HAFYERA

PCC: 728108

Product Artwork CoE

janssen

Shared mailbox: RA-JANBE-GRAPHDES@its.jnj.com

Template Ref. Name: B/L/203/V1
138x90

Tech. info/Spec: N/A

Market: USA

Mat. ID Code: 728108

File Name: 728108.ai
(CC-PC)

BLACK

PMS 485

PMS 915

Diecut (not to be printed)

1. 04-JUN-21 (Santosh)

2. 04-AUG-21 (Santosh)

3. 25-AUG-21 (Luis)

4.

5.

6.

7.

8.

9.

10.

11.

12.

13.

FIGURE 13C

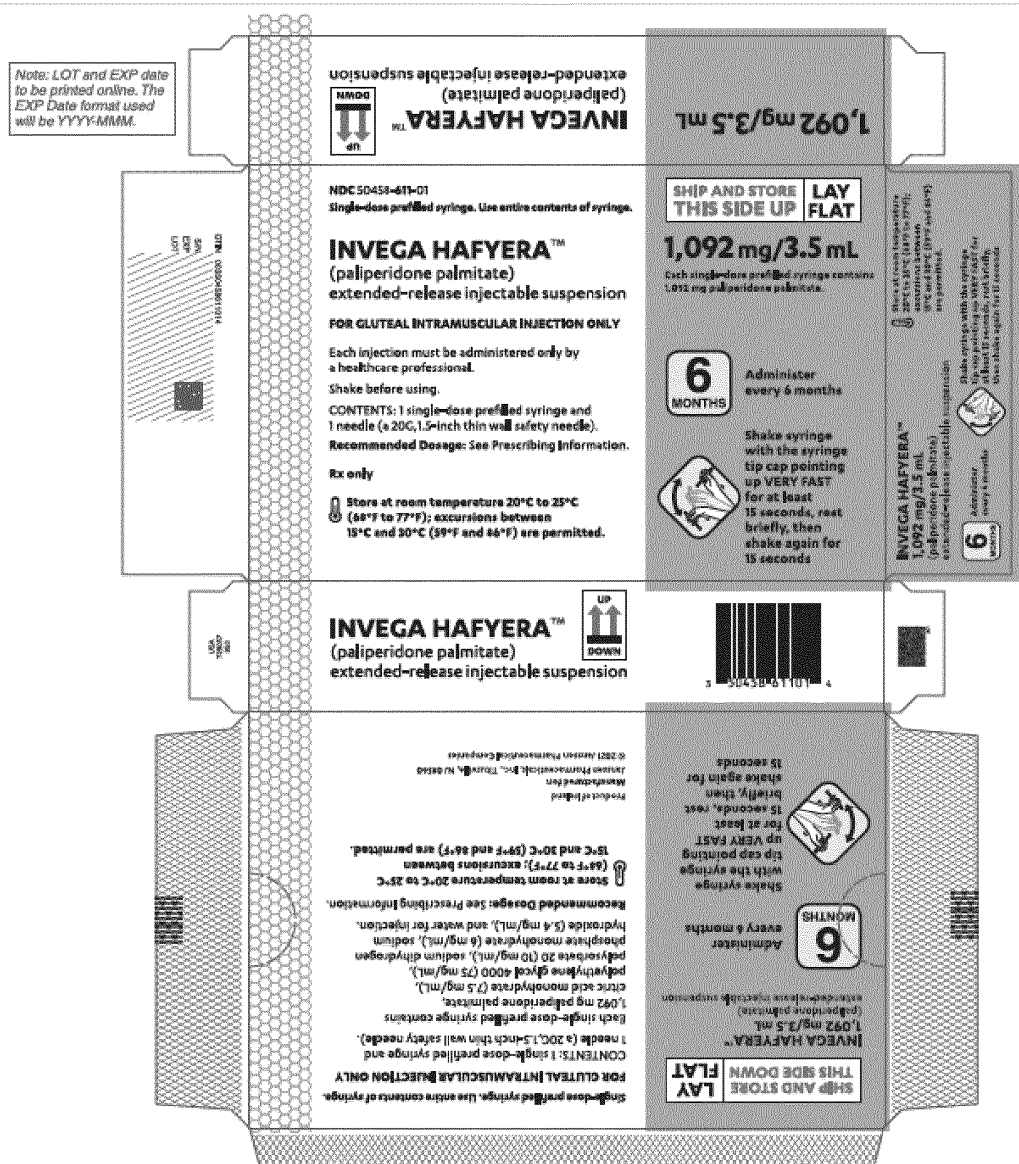
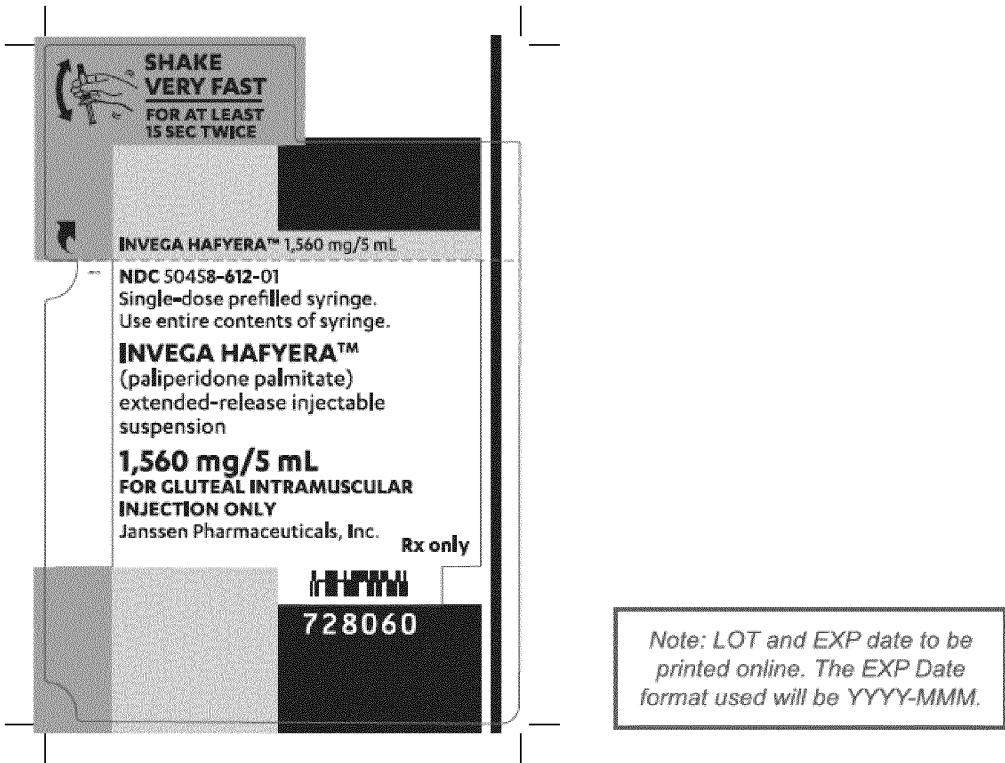


FIGURE 13D

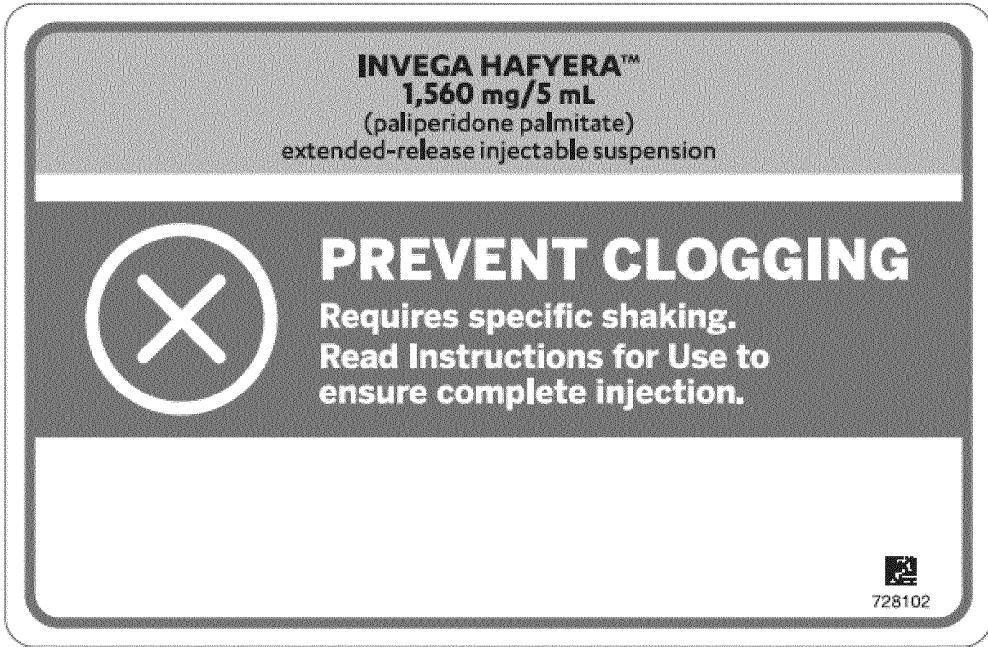
Box INVEGA HAFYERA PCC: 728057		Product Artwork CoE Shared mailbox: RA-JANBE-GRAPHDES@its.jnj.com				janssen 	
<i>Template Ref. Name:</i> B/B/953 PP1MFG ALL & PP3M EX EU/S4 124x39x189 <i>Tech. info/Spec:</i> NA <i>Market:</i> USA <i>Mat. ID Code:</i> 519 <i>File Name:</i> 728057.ai (CC-PC)			BLACK		Diecut (not to be printed)	<i>Date (Designer)</i> 1. 08-JUN-21 (Pradeep)	
			PMS 915		Varnish free	2. 25-JUN-21 (Pradeep)	
			PMS 485		Varnish free & Used for glue	3. 04-AUG-21 (Pradeep)	
			PMS 803		Perforation	4. 05-AUG-21 (Pradeep)	
						5. 23-AUG-21 (Betzabe)	
						6. 23-AUG-21 (Betzabe)	
						7. 25-AUG-21 (Betzabe)	
						8. 25-AUG-21 (Betzabe)	
						9.	
						10.	
						11.	
						12.	
						13.	

FIGURE 13E



Label INVEGA HAFYERA PCC: 728060		Product Artwork CoE janssen	
Template Ref. Name: B/L/305/US/V1 49x70		Shared mailbox: RA-JANBE-GRAPHDES@its.jnj.com	
Tech. info/Spec: N/A Market: USA Mat. ID Code: PCC File Name: 728060.ai (CC-PC)		Black	Date (Designer) 1. 08-JUN-21 (Santosh) 2. 06-AUG-21 (Santosh) 3. 23-AUG-21 (Luis) 4. 23-AUG-21 (Luis) 5. 6. 7. 8. 9. 10. 11. 12. 13.
		Black 2 + Microprint (459116)	
		PMS 802	
		PMS 916	
			Diecut (not to be printed)
			Perforation -----

FIGURE 13F



Label INVEGA HAFYERA PCC: 728102		Product Artwork CoE Shared mailbox: RA-JANBE-GRAPHDES@its.jnj.com		janssen 	
<i>Template Ref. Name:</i> B/L/203/V1 138x90 <i>Tech. info/Spec:</i> N/A <i>Market:</i> USA <i>Mat. ID Code:</i> 728102 <i>File Name:</i> 728102.ai (CC-PC)		BLACK		Diecut (not to be printed)	<i>Date (Designer)</i> 1. 08-JUN-21 (Santosh) 2. 04-AUG-21 (Santosh) 3. 25-AUG-21 (Luis) 4. 5. 6. 7. 8. 9. 10. 11. 12. 13.
		PMS 485			
		PMS 802			

FIGURE 13G

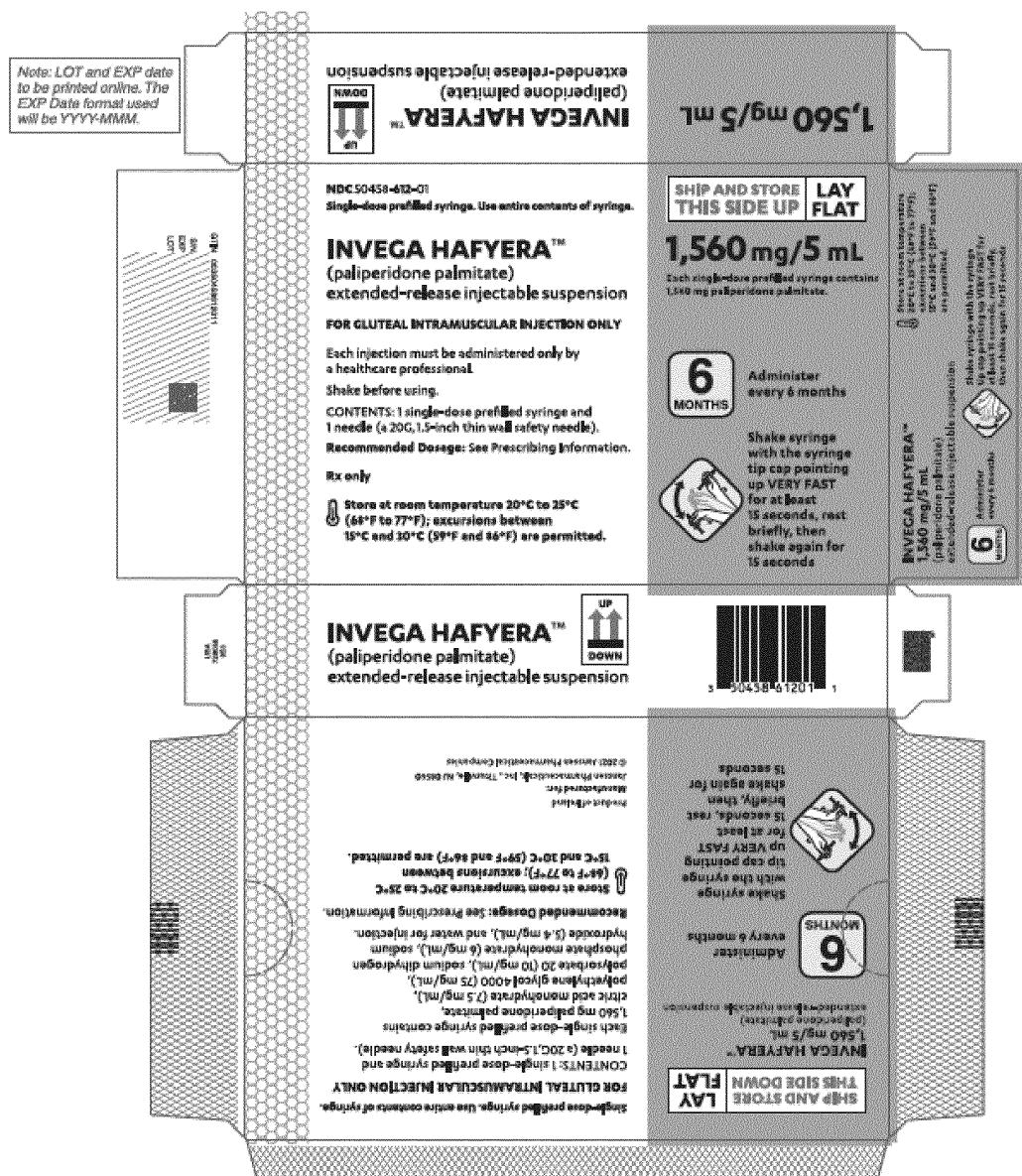


FIGURE 13H

Box INVEGA HAFYERA PCC: 728056		Product Artwork CoE janssen Shared mailbox: RA-JANBE-GRAPHDES@its.jnj.com			
Template Ref. Name: B/B/953 PP1MFG ALL & PP3M EX EU/S4 124x39x189 Tech. info/Spec: NA Market: USA Mat. ID Code: 517 File Name: 728056.ai (CC-PC)		BLACK		Diecut (not to be printed)	Date (Designer) 1. 08-JUN-21 (Pradeep) 2. 25-JUN-21 (Pradeep) 3. 04-AUG-21 (Pradeep) 4. 04-AUG-21 (Pradeep) 5. 06-AUG-21 (Pradeep) 6. 23-AUG-21 (Betzabe) 7. 23-AUG-21 (Betzabe) 8. 25-AUG-21 (Betzabe) 9. 25-AUG-21 (Betzabe) 10. 11. 12. 13.
		PMS 802		Varnish free	
		PMS 485		Varnish free & Used for glue	
		PMS 803		Perforation.....	