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F A X C O V E R S H E E T

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Date: 4/20/00
# of pages: 1+4

MESSAGE

Presentation at the 4.26.00 meeting of orally inhaled and Nasal drug Products. Is there any chance of getting 6 minutes, Please let me know. Thank you.

Sincerely,
Abdul

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TEST	DRAFT BE GUIDANCE METHOD	# OF DETERMINATIONS	DETERMINATIONS (Required/Validated) *
Laser Diffraction for DSD	3x3x3xPnx10x3x2	**8100 if Pn = 5**	2x5x10x6 = **600**
Spray Pattern	3x2x10x3x2	**360**	1x2x10x6 = **120**
Priming	6x10x3x2	**360**	1x10x3 = **30** or 1x2x10x3 = **60**
Re-priming	6x40x3x2	**1440**	1x40x3x2 = **240**
Tail-off profile	30x10x3x2	**1800**	5x10x3x2 = **300**

*preliminary studies are done as a part of method/product development

Non-Profile Statistics: $((\mu_T - \mu_R)^2 + (\sigma^2_T - \sigma^2_R)) / \sigma^2_R \leq \theta$

If $\sigma^2_R > \sigma^2_0$ – Reference scaling

If $\sigma^2_R < \sigma^2_0$ – Constant scaling

Nasal Spray (solution) for Systemic Action-Part of this guidance

HTR.20.2000 3:41PM NO.000 P.3

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TEST	DRAFT CMC GUIDANCE METHOD
IIIF.1. Nasal Spray (performance characteristics)	f. Pump Delivery (by weight)
	g&h. SCU/through container life
	i. Spray Pattern & Plume geometry
	j. DSD
IIIG. Container/Closure	1. Source, chemical composition, Physical dimensions
	2. Control extraction studies
	3. Routine Extraction
	4. Leachables (stability)
IV. Characterization (Drug Product)	A. Priming/Repriming-SCU labeling, etc.
	B-O: etc., etc.,

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CONCLUSIONS

1. BE testing for Nasal Sprays (solution) should involve reduced testing of one lot of reference vs. one lot of test product. There is absolutely no need for 3 lots of reference products.

2. Nasal Spray (solution) for systemic action should be a part of this guidance