DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHO		DATE(S) OF INSPECTION			
Maitland, FL	y Place, Suite 200 32751	6/18/2018-6/22/2018 FEI NUMBER			
(407) 475-4700 Fax: (407) 475-4768			3006228598		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED					
Kristopher J. Fishman, Senior Vice President of Operations					
FIRM NAME STREET ADDRESS					
	1		210 SW 33rd Ave		
CITY, STATE, ZIP CODE, COUN				nile and New Ctenile Days	
		Preparer	r of Sterile and Non-Sterile Drug s		
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.					
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1					
You used a non-pharmaceutical grade component in the formulation of a drug product.					
Specifically, you use (b) (4) (b) (4) produced by (b) (4) to prepare the subformula ID (b) (4) (b) (4) (b) (4) liquid that is used to prepare non-sterile drug suspensions for oral use (prednisolone 10 mg/ml lot 03302018@103), topical non-sterile drug gels (hyaluronic acid sodium salt 2 % lot 03132018@52) and nasal sprays (oxytocin nasal spray lot 06072018@35). You could provide no documentation that this (b) (4) is USP grade as listed in the formula worksheet or (b) (4) for pharmaceutical use.					
	EMPLOYEE(S) SIGNATURE			DATE ISSUED	
SEE REVERSE	Joanne E King, Investigator		2 1 5 2 1	6/22/2018	
OF THIS PAGE			Joanne E King Investigator Signed By 1300174867 Date Signed 06-22-2018 15 46 22		
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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	PECTIONAL O	BSERVATIONS	PAGE 1 of 1 PAGES	