FDA Submission

(Food & Drug Administration Submission)

for

MLR

Form Approved: OMB No. 0910-0001, Expiration Date: December 31, 2017; see PRA Statement on last page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL LABELING FOR DRUGS AND BIOLOGICS FOR HUMAN USE

1. Date Submitted: 11/01/2018

2. Label Review Number (Biologics): Job-11141121

3. NDA/ANDA/AADA or BLA/PMA Type: PMA Number: 11141121

☐ Single product ☐ Multiple products

For multiple products, submit completed form and specimen of advertising / promotional materials to one application of choice, and attach separate sheet addressing items 3-5 for remainder of products. Refer to No. 3 on instruction sheet.

NOTE: FORM FDA 2253 IS REQUIRED BY LAW. REPORTS ARE REQUIRED FOR APPROVED NDAS AND ANDAS (21 CFR 314.81).

4. Proprietary Name: DJ Test -1

5. Established Name: Joe

Product Code No.: Job-11141121

6. Package Insert Date and ID Number (Latest final printed labeling): 11/01/2018

7. Manufacturer Name: Joe

License No. (Biologics):

8. Advertisement / Promotional Labeling Materials

a. **Please check only one:** ☐ Professional ☐ Consumer

Material Type (use FDA codes) b.	Dissemination / Publication Date c.	Material ID Code d.	Material Description e.
www-website		Audio	Audi Media

f. Comments

9. Applicant's (or Agent's) Return Address

Address 1 *(Street address, P.O. box, company name c/o)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City | State/Province/Region

Country | ZIP or Postal Code

10. Responsible Official's (or Agent's)

a. Telephone Number *(Include area code)*

b. FAX Number *(Include area code)*

c. Email Address

11. Typed Name and Title of Responsible Official or Agent	12. Signature of Responsible Official or Agent	13. Date
		11/01/2018

14. For CBER Products Only *(Check one)*

☐ Draft ☐ Final

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW. ***

The burden time for this collection of information is estimated to average 2 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
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