DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-620]

Bulk Manufacturer of Controlled Substances Application: Benuvia Therapeutics Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESS: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on December 4, 2019, Benuvia Therapeutics Inc., 2700 Oakmont Drive, Round Rock, Texas 78665 applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

<table>
<thead>
<tr>
<th>Controlled Substance</th>
<th>Drug Code</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marihuana</td>
<td>7360</td>
<td>I</td>
</tr>
<tr>
<td>Tetrahydrocannabinols</td>
<td>7370</td>
<td>I</td>
</tr>
</tbody>
</table>

The company plans to manufacture the above-listed controlled substances in bulk to produce finished dosage forms and conduct research to develop new drug products and for
clinical studies. In reference to drug codes 7360 (Marihuana), and 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture these drugs as synthetic. No other activities for these drug codes are authorized for this registration.

William T. McDermott,  
*Assistant Administrator.*

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