



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
10 Waterview Blvd, 3rd FL
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January 18, 2018

Mr. Luboslav Blahut
Director/Owner
EL spol. s.r.o.
Radlinskeho 17A
Spisska Nova Ves, Kosicky, 052 01 Slovakia

Dear Mr. Blahut:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises at Radlinskeho 17A, Spisska Nova Ves, Kosicky, 052 01 Slovakia on November 20, 2017 through November 21, 2017 on behalf of the U.S. Food and Drug Administration (FDA). When the Agency concludes that an inspection is "closed," under 21 C.F.R. 20.64 (d) (3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of that effort. The copy being provided to you contains the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the FOIA and 21 C.F.R. Part 20. This, however, does not preclude you from requesting additional information available under FOIA.

If there is any question about the released information, feel free to contact:

Margaret Sands, SCSO
U.S. Food and Drug Administration
1 Montvale Avenue, 4th Floor
Stoneham, MA 02180
781-587-7483

Sincerely,

Margaret
M. Sands -S

Digitally signed by Margaret M.
Sands -S
DN: cn=S, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
c=US, email=Margaret.M.Sands-S
7623, cn=Margaret M. Sands -S
Date: 2018.01.19 13:59:36 -0500

Margaret Sands
Supervisory Consumer Safety Officer

LCJ
1 Enclosure

Office of Pharmaceutical Quality Operations, Division of Pharmaceutical Quality Operations I
New England District Office: One Montvale Avenue, 4th Floor Stoneham, MA 02180-3500 T- (781) 587-7500 F- (781) 587-7556
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