



**FDA** **U.S. FOOD & DRUG**  
**ADMINISTRATION**

OFFICE OF REGULATORY AFFAIRS  
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

U.S. Food and Drug Administration  
Division of Pharmaceutical Quality Operations I  
10 Waterview Blvd, 3<sup>rd</sup> FL  
Parsippany, NJ 07054  
Telephone: (973) 331-4900  
FAX: (973) 331-4969  
[www.fda.gov](http://www.fda.gov)

May 1, 2020

Ms. Rosemary E. Mihalko, RPh  
Owner  
Hieber's Pharmacy  
3500 5<sup>th</sup> Avenue  
Pittsburgh, PA 15213-3337

Dear Ms. Mihalko:

We are enclosing a copy of the Establishment Inspection Reports (EIRs) for the inspections conducted at your facility, Hieber's Pharmacy, located at 3500 5<sup>th</sup> Avenue, Pittsburgh, PA 15213, from September 8, 2014, through September 18, 2014, from January 23, 2017, through February 17, 2017, and from July 8, 2019, through July 17, 2019, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Pennsylvania State Board of Pharmacy for follow up.

When the Agency considers an inspection to be "closed" under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

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

**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  
New York District Office: 158-15 Liberty Ave Jamaica, NY 11433 T-(718) 340-7000 F-(718) 662-5661  
Philadelphia District Office: US Customs House Room 900, 200 Chestnut St. Philadelphia, PA 19106 T- (215) 597-4390 F-(215) 597-4660  
Baltimore District Office: 6000 Metro Drive, Suite 101 Baltimore, MD 21215 T-410-779-5455 F- 410-779-5407

If there is any question about the released information, please contact Yvette Johnson, Compliance Officer at email: [yvette.johnson@fda.hhs.gov](mailto:yvette.johnson@fda.hhs.gov).

Sincerely,

Diana  
Amador-  
toro -S

Digitally signed by Diana Amador-  
toro -S  
DN: c=US, o=U.S. Government,  
ou=HHS, ou=FDA, ou=People,  
0.9.2342.19200300.100.1.1=1300011  
579, cn=Diana Amador-toro -S  
Date: 2020.05.01 14:09:01 -04'00'

Diana Amador-Toro  
Program Division Director  
Office of Pharmaceutical Quality Operations  
Division I/New Jersey District

Enclosure: EIRs and SHL

Cc: Pennsylvania State Board of Pharmacy (cover letter only)  
Melanie Zimmerman  
Executive Secretary  
2601 N. 3rd St,  
Harrisburg, PA 17110