

EXHIBIT E

Next Page

Export Data

Import Data

Reset Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration APPLICATION TO MARKET A NEW OR ABBREVIATED NEW DRUG OR BIOLOGIC FOR HUMAN USE <i>(Title 21, Code of Federal Regulations, Parts 314 & 601)</i>		Form Approved: OMB No. 0910-0338 Expiration Date: December 31, 2017 See PRA Statement on page 3.	
		1. Date of Submission (mm/dd/yyyy) 03/XX/2015	
APPLICANT INFORMATION		2. Name of Applicant Ferrum Ferro Capital, LLC	
3. Telephone Number (Include country code if applicable and area code) 1.302.514.0050		4. Facsimile (FAX) Number (Include country code if applicable and area code) 1.509.351.7892	
5. Applicant Address			
Address 1 (Street address, P.O. box, company name c/o) 717 N. Union Street, #78		Email Address kb@ferrumferro.com	
Address 2 (Apartment, suite, unit, building, floor, etc.)			
City Wilmington	State/Province/Region DE	U.S. License Number if previously issued	
Country United States of America	ZIP or Postal Code 19805-3031		
6. Authorized U.S. Agent (Required for non-U.S. applicants)			
Authorized U.S. Agent Name		Telephone Number (Include area code)	
Address 1 (Street address, P.O. box, company name c/o)		FAX Number (Include area code)	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Email Address	
City	State		
ZIP Code			
PRODUCT DESCRIPTION		7. NDA, ANDA, or BLA Application Number 208338	8. Supplement Number (If applicable)
9. Established Name (e.g., proper name, USP/USAN name) Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution			
10. Proprietary Name (Trade Name) (If any) Combivious			
11. Chemical/Biochemical/Blood Product Name (If any)			
12. Dosage Form Solution/Drops	13. Strengths 0.2%;EQ 0.5% Base	14. Route of Administration Ophthalmic	
15. Proposed Indication for Use Combivious (brimonidine tartrate/timolol maleate ophthalmic solution) 0.2%/0.5% will be an alpha-adrenergic receptor agonist with a beta-adrenergic receptor inhibitor indicated for the reduction of elevated intraocular pressure (IOP) in patients with glaucoma or ocular hypertension who require adjunctive or replacement therapy due to inadequately controlled IOP.		Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, provide the Orphan Designation number for this indication: <input type="text"/>	
		Contin. Page for #15	
APPLICATION INFORMATION		16. Application Type (Select one) <input type="checkbox"/> New Drug Application (NDA) <input type="checkbox"/> Biologics License Application (BLA) <input checked="" type="checkbox"/> Abbreviated New Drug Application (ANDA)	
17. If an NDA, identify the type <input type="checkbox"/> 505 (b)(1) <input type="checkbox"/> 505 (b)(2)		18. If a BLA, identify the type <input type="checkbox"/> 351 (a) <input type="checkbox"/> 351 (k)	
19. If a 351(k), identify the biological reference product that is the basis for the submission. Name of Biologic: _____ Holder of Licensed Application: _____			
20. If an ANDA, or 505(b)(2), identify the listed drug product that is the basis for the submission. Name of Drug: <u>Combigan</u> Application Number of Relied Upon Product: <u>N021398</u>			
Indicate Patent Certification(s): <input type="checkbox"/> P1 <input type="checkbox"/> P2 <input checked="" type="checkbox"/> P3 <input type="checkbox"/> P4 <input type="checkbox"/> Section viii - MOU <input type="checkbox"/> Statement of no relevant patents			
21. Submission (Select one) <input checked="" type="checkbox"/> Original <input type="checkbox"/> Labeling Supplement <input type="checkbox"/> CMC Supplement <input type="checkbox"/> Efficacy Supplement <input type="checkbox"/> Annual Report <input type="checkbox"/> Product Correspondence <input type="checkbox"/> REMS Supplement <input type="checkbox"/> Postmarketing Requirements or Commitments <input type="checkbox"/> Periodic Safety Report <input type="checkbox"/> Other (Specify): _____			