

<div>DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION</div> <div>APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE</div> <div>(Title 21, Code of Federal Regulations, Parts 314 & 601)</div>		<div>Form Approved: OMB No. 0910-0338 Expiration Date: March 31, 2003 See OMB Statement on page 2.</div> <div>FOR FDA USE ONLY</div> <div>APPLICATION NUMBER</div>
APPLICANT INFORMATION		
NAME OF APPLICANT Good Pharmaceuticals		DATE OF SUBMISSION 5/01/01
TELEPHONE NO. (Include Area Code) xxx-xxx-xxxx		FACSIMILE (FAX) Number (Include Area Code) xxx-xxx-xxxx
APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued): 202 New Drug Road Pharmaceutical, Maryland, USA 00000		AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE Not Applicable
PRODUCT DESCRIPTION		
NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) N031025		
ESTABLISHED NAME (e.g., Proper name, USP/USAN name)		PROPRIETARY NAME (trade name) IF ANY Blockbuster
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (If any)		CODE NAME (If any) CYBLBU
DOSAGE FORM: Capsule	STRENGTHS: 200mg	ROUTE OF ADMINISTRATION: Oral
(PROPOSED) INDICATION(S) FOR USE: Anti-Depressant		
APPLICATION INFORMATION		
APPLICATION TYPE (check one) <input checked="" type="checkbox"/> NEW DRUG APPLICATION (21 CFR 314.50) <input type="checkbox"/> ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94) <input type="checkbox"/> BIOLOGICS LICENSE APPLICATION (21 CFR Part 601)		
IF AN NDA, IDENTIFY THE APPROPRIATE TYPE <input checked="" type="checkbox"/> 505 (b)(1) <input type="checkbox"/> 505 (b)(2)		
IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION Name of Drug Holder of Approved Application		
TYPE OF SUBMISSION (check one) <input checked="" type="checkbox"/> ORIGINAL APPLICATION <input type="checkbox"/> AMENDMENT TO A PENDING APPLICATION <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> PRESUBMISSION <input type="checkbox"/> ANNUAL REPORT <input type="checkbox"/> ESTABLISHMENT DESCRIPTION SUPPLEMENT <input type="checkbox"/> EFFICACY SUPPLEMENT <input type="checkbox"/> LABELING SUPPLEMENT <input type="checkbox"/> CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT <input type="checkbox"/> OTHER		
IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____		
IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY <input type="checkbox"/> CBE <input type="checkbox"/> CBE-30 <input type="checkbox"/> Prior Approval (PA)		
REASON FOR SUBMISSION Obtain Marketing Approval		
PROPOSED MARKETING STATUS (check one) <input type="checkbox"/> PRESCRIPTION PRODUCT (Rx) <input type="checkbox"/> OVER THE COUNTER PRODUCT (OTC)		
NUMBER OF VOLUMES SUBMITTED 5	THIS APPLICATION IS <input checked="" type="checkbox"/> PAPER <input type="checkbox"/> PAPER AND ELECTRONIC <input type="checkbox"/> ELECTRONIC	
ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.) Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.		
Good Pharmaceuticals, 202nNew Drug Road, Pharmaceutical, Maryland, 00000; CFN#1 See Attachment		
Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)		
IND xxxxxx		

This application contains the following items: (Check all that apply)		
	1. Index	
	2. Labeling (check one) <input checked="" type="checkbox"/> Draft Labeling <input type="checkbox"/> Final Printed Labeling	
X	3. Summary (21 CFR 314.50 (c))	
X	4. Chemistry section	
X	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)	
X	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)	
X	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)	
X	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)	
X	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)	
X	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))	
X	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)	
X	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)	
X	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)	
X	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)	
X	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)	
X	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))	
X	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))	
X	15. Establishment description (21 CFR Part 600, if applicable)	
X	16. Debarment certification (FD&C Act 306 (k)(1))	
X	17. Field copy certification (21 CFR 314.50 (k)(3))	
X	18. User Fee Cover Sheet (Form FDA 3397)	
X	19. Financial Information (21 CFR Part 54)	
X	20. OTHER (Specify)	
CERTIFICATION		
I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:		
1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.		
2. Biological establishment standards in 21 CFR Part 600.		
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.		
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.		
5. Regulations on making changes in application in FD&C Act Section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.		
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.		
7. Local, state and Federal environmental impact laws.		
If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.		
The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.		
Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.		
SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
Allswell Titer	Allswell Titer, Director, Regulatory Affairs	5/1/01
ADDRESS (Street, City, State, and ZIP Code)	Telephone Number	
202 New Drug Road; Pharmaceutical, Maryland 00000	(xxx) xxx-xxxx	
Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:		
Department of Health and Human Services Food and Drug Administration CDER, HFD-99 1401 Rockville Pike Rockville, MD 20852-1448	Food and Drug Administration CDER, HFD-94 12420 Parklawn Dr., Room 3046 Rockville, MD 20852	An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.