DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
APPLICATION TO MARKET A NEW DRUG, BIOLOGIC,
OR AN ANTIBIOTIC DRUG FOR HUMAN USE
(Title 21 Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338 Expiration Date: August 31, 2005 See OMB Statement on page 2.

APPLICATION NUMBER  APPLICANT INFORMATION  NAME OF APPLICANT  EIL Lilly and Company  August 10, 2004  FACSIMILE (FAX) Number (Include Area Code)  317-276-1652  317-276-1652  317-276-1652  APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Meil Code, and U.S. License number if previously issued):  Lilly Corporate Center Indianapolis, IN 46285  PRODUCT DESCRIPTION  NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued): NAME (e.g., Proper name, USP/USAN name)  FROUNDED OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued): NDA 18-936  PROPRIETARY NAME (reade name): IF ANY  FILOXOSIRE Hydrochloride  CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (If any)  DOSAGE FORM:  Capsule, Pulvule, Liquid  Tong, 20m, 20mg/5mL, 40mg, 90mg  Oral  PROPOSED) INDICATION(S): FOR USE:  AN ADDA, OR 696(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT TIME IS THE BASIS FOR THE SUBMISSION  ABBREVIATED NEW DRUG APPLICATION (21 CFR 914.50)  PROPOSED INDICATION(S)  FAN NDA, IDENTIFY THE APPROPRIATE CATEGORY  PROPEDIAL SUBMISSION (Index One)  PROPICATION INFORMATION  ABBREVIATED NEW DRUG APPLICATION (21 CFR 914.50)  BIOLOGICS LICENSE APPLICATION (21 CFR 916.50)  PROPIDED SUBMISSION (Index One)  PROPIDED SUBMISSION (INDICATION)  PROPIDED SUB	(Title 21, Code of Federal Regulations, Parts 314 & 601)			FOR FDA USE ONLY
Ell Lilly and Company  August 10, 2004  FELEPHONE NO, (nacular Area Code)  317-276-2000  APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail  317-276-1652  ALTH-POREZO U.S. AGENT NAME & ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail  ALTH-POREZO U.S. AGENT NAME & ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail  ALTH-POREZO U.S. AGENT NAME & ADDRESS (Number, Street, City, State, Country, ZIP Code, redightone & FAX number) IF APPLICABLE  ALTH-POREZO U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE  ALTH-POREZO U.S. AGENT NAME (number) IF APPLICABLE  APPLICATION NUMBER (if rany)  CODE NAME (number) IF APPLICABLE  CAPSALLE OF NAME (number name) IF AVIV  FOUNDATION OF PRODUCT NAME (number)  FOUNDATION OF PRODUCT (nu				APPLICATION NUMBER
FILEPHONE NO. (Include Area Code)  ATT-276-1632  AUTHORIZED U.S. AGENT NAME & ADDRESS (Alumber, Street, City, State, Country, ZIP Code or Mail Code, and U.S. Lorens number if previously issued):  AUTHORIZED U.S. AGENT NAME & ADDRESS (Alumber, Street, City, State, Country, ZIP Code or Mail Code, and U.S. Lorens number if previously issued):  AUTHORIZED U.S. AGENT NAME & ADDRESS (Alumber, Street, City, State, Country, ZIP Code, telephone & FAX number) if APPLICABLE  PRODUCT DESCRIPTION  NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued): NDA 18-936  FINANCIAL ENGINE HYDROGOD PRODUCT NAME (If any)  FILEPHONE HYDROGOD PRODUCT NAME (If any)  PROPORIETARY NAME (Include name) IF ANY  Prozac®  FILEPHONE HYDROGOD PRODUCT NAME (If any)  CODE NAME	APPLICANT INFORMATION			
FREEPHONE NO. (Include Area Code)   STA-276-2000   STA-276-1652	NAME OF APPLICANT		DATE OF SUBMISSION	
FECSIMUE (FAX) Number (Include Area Code)   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-276-1652   317-2	Eli Lilly and Company		August 10, 2004	
AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail ZiP Code, and U.S. License number if previously issued):  Lilly Corporate Center indianapolis, IN 46285    AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZiP Code, telephone & FAX number) IF APPLICABLE   APPLICATION NUMBER (IF previously issued)	TELEPHONE NO. (Include Area Code)		FACSIMILE (FAX) Number (Include Area Code)	
Code, and U.S. License number if previously issued):  Lilly Corporate Center Indianapolis, IN 46285  PRODUCT DESCRIPTION  NEW DRUG OR ANTIBIOTIC APPLICATION NUMSER, OR BIOLOGICS LICENSE APPLICATION NUMBER (if previously issued). NDA 18-936  ESTABLISHED NAME (e.g., Proper name, USPIUSAN name)  Fluxostine Hydrochloride  PROPRIETAR' NAME (rade name) if ANY  Fluxostine Hydrochloride  CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (if any)  CODE NAME (if any)  CODE NAME (if any)  CODE NAME (if any)  CODE NAME (if any)  DOSAGE FORM:  Capsule, Pulvule, Liquid  10mg,20m,20mg/5mL,40mg,90mg  Oral  PROPOSED) INDICATION(S) FOR USE:  All Approved incidations  APPLICATION INFORMATION  APPLICATION INFORMATION  APPLICATION INFORMATION  APPLICATION INFORMATION  FAN NOA, DENTIFY THE APPROPRIATE TYPE  BIOLOGICS UCENSE APPLICATION (21 CFR 914.50)  BIOLOGICS UCENSE	317-276-2000		317-276-1652	
Indianapolis, IN 46285  PRODUCT DESCRIPTION  NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (if previously issued) NDA 18-936  ESTABLISHED NAME (ite.g., Proper name, USPPUSAN name)  Fluoxetine Hydrochloride  PROPRIETARY NAME (ite.de name) IF ANY  Fluoxetine Hydrochloride  PROPRIETARY NAME (ite.de name) IF ANY  Prozac®  CODE NAME (it any)  CODE NAME (it any)  DOSAGE FORM:  STRENGTHS:  ROUTE OF ADMINISTRATION:  Capsule, Pulvule, Liquid  10mg,20m,20mg/5mL,40mg,90mg  Oral  PROPOSED) INDICATION(S) FOR USE:  All Approved Indications  APPLICATION INFORMATION  PRELICATION TYPE  (incerc one)  BNEW DRUG APPLICATION (21 CFR 314.50)  BROUGOIS LICENSE APPLICATION (21 CFR 748.60)  FAN NOA, DENTIFY THE APPROPRIATE TYPE  BOS (b)(1)  FAN ANDA, OR SOS(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION  Holder of Approved Application  TYPE OF SUBMISSION (inheck one)  CHEMISTRY MAMPLACHINER AND CHEMISTRY MAMPLACHINER AND CONTROLS SUPPLEMENT  CHEMISTRY MAMPLACHINER AND CONTROLS SUPPLEMENT  CHEMISTRY MAMPLACHINER AND CONTROLS SUPPLEMENT  FA SUBMISSION OF PARTILL APPLICATION, PROVIDE LISTED DATE OF AGREEMENT TO PARTIAL SUBMISSION  FRESON FOR SUBMISSION  PROPRIEDED MARRIETTED  CHEMISTRY MAMPLACHINER AND CONTROLS SUPPLEMENT  THIS APPLICATION IS CHEMISSION  PROPRIEDED MARRIETTED  THIS APPLICATION IS CHEMISTON AND CONTROLS SUPPLEMENT  PROPRIEDED MARRIETTED  THIS APPLICATION IS CHEMISTON OF THE SUBMISSION  PROPRIEDED MARRIETTED  THIS APPLICATION IS CHEMISTON OF THE PAPER AND ELECTRONIC CHEMISTED SUBMISSION  PROPRIEDED MARRIETTED  THIS APPLICATION IS CHEMISTON HORSELD THE COUNTER PRODUCT (OTC)  NUMBER OF VOLUMES SUBMITTED  THIS APPLICATION IS CHEMISTON HORSELD THE COUNTER PRODUCT (OTC)  PROPRIEDED MARRIETTED  THIS APPLICATION IS CHEMISTON HORSELD THE COUNTER PRODUCT (OTC)  THIS APPLICATION IS CHEMISTON HORS	APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):		• • • • • • • • • • • • • • • • • • • •	
NEW DRUG OR ANTBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) NDA 18-936  ESTABLISHED NAME (e.g., Proper name, USP/USAN name) FIGURATION PROPRIETTAY NAME (trade name) IF ANY Prozac®  CODE NAME (et.g., Proper name, USP/USAN name) FIGURATION PROPRIETTAY NAME (trade name) IF ANY Prozac®  CODE NAME (if any)  Oral  PROPOSED) INDICATION(S) FOR USE: All Approved Indications  APPLICATION INFORMATION  APPLICATION INFORMATION  APPLICATION (21 CFR 314.50) BIOLOGICS LICENSE APPLICATIO	Indianapolis, IN 46285			
ESTABLISHED NAME (e.g., Proper name, USP/USAN name)   PROPRIETARY NAME (trade name) IF ANY     Prozace®	PRODUCT DESCRIPTION			
Fluoxetine Hydrochloride Prozac®  CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (If any)  CODE NAME (If any)  CODE NAME (If any)  CODE NAME (If any)  DOSAGE FORM:  Capsule, Pulvule, Liquid 10mg,20m,20mg/5mL,40mg,90mg Oral  PROPOSED) INDICATION(S) FOR USE:  All Approved Indications  APPLICATION 1FORMATION  APPLICATION 1FORMATION  APPLICATION 1FORMATION  FAN NDA, IDENTIFY THE APPROPRIATE TYPE \$505 (b)(1) \$505 (b)(2)  FAN NDA, (DENTIFY THE APPROPRIATE TYPE \$505 (b)(1) \$505 (b)(2)  FAN NDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION  Name of Drug   Holder of Approved Application   ARRIVANDA APPLICATION   ARRIVANDA APPLICATION   RESUBMISSION    PRESUBMISSION (check one)   ORIGINAL APPLICATION   AMENDMENT TO APPLICATION   RESUBMISSION    PRESUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:  FA SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:  FA SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:  FA SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:  FERSON FOR SUBMISSION  PREASON FOR SUBMISSION  THIS APPLICATION IS   PAPER   PAPER AND ELECTRONIC   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, cells that on number (CFN), DMF number, and manufacturing to the page 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.	NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, C	R BIOLOGICS LICENSE A	PPLICATION NUMBER (If previo	ously issued) NDA 18-936
CODE NAME (If any)  COD NOT AND SUBMISSION  COD NAME (IT any)  COD NAME (I	ESTABLISHED NAME (e.g., Proper name, USP/USAN nar	ne)	PROPRIETARY NAME (trade name) IF ANY	
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Capsule, Pulvule, Liquid 10mg,20m,20mg/5mL,40mg,90mg Oral  (PROPOSED) INDICATION(S) FOR USE:  All Approved Indications  APPLICATION INFORMATION  APPLICATION INFORMATION  APPLICATION INFORMATION  APPLICATION INFORMATION  APPLICATION 17PE  (check one)	CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (If	HEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (If any)		CODE NAME (If any)
PROPOSED  INDICATION(S) FOR USE:	DOSAGE FORM:	STRENGTHS:		ROUTE OF ADMINISTRATION:
PROPOSED  INDICATION(S) FOR USE:	Capsule, Pulvule, Liquid	10mg,20m,20mg/5	mL,40mg,90mg	Oral
APPLICATION INFORMATION  APPLICATION TYPE (check one)	(PROPOSED) INDICATION(S) FOR USE:	<u> </u>		
APPLICATION TYPE  (check one)  NEW DRUG APPLICATION (21 CFR 314.50)  ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)    BIOLOGICS LICENSE APPLICATION (21 CFR Part 601)    505 (b)(2)   FAN NDA, IDENTIFY THE APPROPRIATE TYPE  SO5 (b)(1)    505 (b)(2)   FAN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION   Name of Drug	All Approved Indications			
APPLICATION TYPE  (check one)  NEW DRUG APPLICATION (21 CFR 314.50)  ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)    BIOLOGICS LICENSE APPLICATION (21 CFR Part 601)    505 (b)(2)   FAN NDA, IDENTIFY THE APPROPRIATE TYPE  SO5 (b)(1)    505 (b)(2)   FAN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION   Name of Drug	APPLICATION INFORMATION			
Name of Drug Holder of Approved Application    PRESUBMISSION (check one)	☐ BIOLOGICS LICENSE APPLICATIF AN NDA, IDENTIFY THE APPROPRIATE TYPE	ATION (21 CFR Part 601)  505 (b)(1)	505 (b)(2)	
TYPE OF SUBMISSION (check one)				SUBMISSION
PRESUBMISSION ANNUAL REPORT STABLISHMENT DESCRIPTION SUPPLEMENT OTHER  IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:  IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY CBE CBE-30 Prior Approval (PA)  REASON FOR SUBMISSION  Briefing Document for FDA meeting  PROPOSED MARKETING STATUS (check one) PRESCRIPTION PRODUCT (Rx) OVER THE COUNTER PRODUCT (OTC)  NUMBER OF VOLUMES SUBMITTED 1 THIS APPLICATION IS PAPER PAPER AND 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.	Name of Drug	Ho	older of Approved Application _	
REASON FOR SUBMISSION Briefing Document for FDA meeting PROPOSED MARKETING STATUS (check one)  PRESCRIPTION PRODUCT (Rx) OVER THE COUNTER PRODUCT (OTC)  NUMBER OF VOLUMES SUBMITTED  1 THIS APPLICATION IS PAPER PAPER AND 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.  NA	☐ PRESUBMISSION ☐ ANNUAL REPORT	ESTABLISHMENT DESCRIP	PTION SUPPLEMENT	EFFICACY SUPPLEMENT
Briefing Document for FDA meeting  PROPOSED MARKETING STATUS (check one)  PRESCRIPTION PRODUCT (Rx) OVER THE COUNTER PRODUCT (OTC)  NUMBER OF VOLUMES SUBMITTED  1 THIS APPLICATION IS PAPER PAPER AND ELECTRONIC 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.  NA	IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE	ELETTER DATE OF AGRE	EMENT TO PARTIAL SUBMISS	NON:
Briefing Document for FDA meeting  PROPOSED MARKETING STATUS (check one)  PRESCRIPTION PRODUCT (Rx) OVER THE COUNTER PRODUCT (OTC)  NUMBER OF VOLUMES SUBMITTED  1 THIS APPLICATION IS PAPER PAPER AND 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.  NA	IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CAT	EGORY CBE C	CBE-30 🗆 Prior Appro	oval (PA)
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Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)				
	Cross References (list related License Application	s, INDs, NDAs, PMAs, 5	10(k)s, IDEs, BMFs, and DM	Fs referenced in the current application)

This application contains the following items: (Check all that apply)						
	1. Index					
	2. Labeling (check one)	ling Final Printed Labeling				
	3. Summary (21 CFR 314.50 (c))					
	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)					
	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)					
	7. Clinical Microbiology (e.g., 21 CFR 314.50(d	()(4))				
	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)					
	10. Statistical section (e.g., 21 CFR 314.50(d)(6	); 21 CFR 601.2)				
	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)					
	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))					
	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))					
	20. OTHER (Specify) Response to FDA request – Briefing Document for FDA meeting					
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  Barbara E. Arning, M.D., Manager  U.S. Regulatory Affairs						
U.S. Regulatory Affairs  ADDRESS (Street, City, State, and ZIP Code)  Telephone Number						
Lilly Corporate Center ( 317 ) 276-1489						
Indianapo	Indianapolis, IN 46285					

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 Food and Drug Administration CDER (HFD-94) 12229 Wilkins Avenue 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.