OMB No. 2010-0032
Expiration Date: 06/30/03

National Environmental Performance Track
U.S. Environmental Protection Agency

Annual Performance Report Form

Facility Name: Ortho Biologics, LLC

Performance Track ID #: A020015

Annual Performance Report #: 1

Reporting Year: 2001

Due Date: July 1, 2002

Section A

General Facility Information

To the extent possible, EPA will pre-complete items A.1-A.8 for you. Please ensure that the information in A.1-A.8 below is accurate, complete, and up to date. Please supply or revise any information as necessary and then check the box to the left of the item(s) to indicate where changes have been made. Items A.9 and A.10 cannot be pre-completed; please respond as directed in A.9 and A.10 below.

Did you make changes? If so, check box.

A.1 ☐ Name of your facility: Ortho Biologics, LLC

A.2 ☐ Name of your parent company: Johnson and Johnson

A.3 ☐ Facility contact person for the Performance Track program

Name: Mr./Mrs./Ms./Dr. Ramon Rijos

Title:

Phone: (787) 884-1130 Fax: E-mail:

A.4 ☐ Facility's location

Street Address: PO BOX 33333

Street Address (cont.):

City/State/Zip Code: Manati/PR/00674

A.5 ☐ Facility's website address (if any):

A.6 ☐ Number of employees (full-time equivalents) who currently work in the facility:

☐ Fewer than 50 ☐ 50 - 99 ☒ 100 - 499 ☐ 500 - 1000 ☐ More than 1000

A.7 ☐ Does your company meet the Small Business Administration definition of a small business for your sector? ☐ Yes ☒ No

A.8 ☐ North American Industrial Classification System (NAICS) Code(s) that are used to classify business at the facility: _____ _____ _____ _____ _____

A.9 ☐ In your application and, perhaps, in previous annual performance reports, you described what your facility does or makes. Have there been any (additional) changes to your facility's list of products and/or activities? If so, please list them in the space below. ☐ Yes ☐ No

A.10 ☐ Please update the list of environmental requirements that apply to your facility. In the space below, indicate any changes that have taken place during this reporting period. If you have no changes to report, please write "No changes."

Section B

Environmental Management System

B.1 **Environmental Management System Assessment.** Please summarize EMS assessments conducted *during the year*. Attach additional sheets as necessary.

a. Was an EMS audit or other assessment done by an independent third party?
☒ Yes ☐ No

If yes, please provide the *type* (e.g., ISO 14001 certification), the *scope*, and the *dates* (mo/yr) of each assessment.

ISO Certification by ERM-CVS, 03/01

Every ISO 14001 certified Johnson & Johnson facility undergoes an annual surveillance audit by its registrar as required by ISO certification requirements.

b. Was an internal or corporate EMS audit conducted? ☒ Yes ☐ No

If yes, please provide the *scope* and the *dates* (mo/yr) of each audit.

03/01

Every J&J facility conducts an annual self-assessment against the J&J worldwide environmental standards, which include the ISO 14001 EMS standards per J&J requirement.

c. Was a compliance audit conducted? ☒ Yes ☐ No

If yes, please provide the *scope* and the *dates* (mo/yr) of each audit, and indicate *who* conducted the audit(s) (e.g., facility staff, corporate groups, third party).

All ISO 14001, J&J corporate, and facility self-assessments include a compliance review component.

d. (Optional) If you would like to describe any other audits or inspections that were conducted at your facility, please do so here.

Section B

(continued)

B.1

e. Briefly summarize corrective actions taken and other improvements made as a result of your EMS assessments and compliance audits.
Attention and priority are given to correcting all regulatory non-compliance. J&J facilities strive for beyond compliance. Therefore, many issues identified in a facility's MAP are for continuous improvement.

f. Has your facility corrected all instances of potential non-compliance and EMS non-conformance identified during your audits and other assessments?

☐ Yes ☐ No ☐ No such instances identified

If no, please explain your plans to correct these instances. A facility Management Action Plan (MAP) is developed/updated after every ISO (EMS), J&J Corporate, or self-assessment. The MAP identifies all the non-conformance issues, the corrective actions, person(s) responsible for each corrective action, and target dates for completing each corrective action. The facility's management board reviews the MAP on a regular basis. A MAP update is forwarded to J&J Corporate Environmental Affairs for review twice a year, once of which must contain the signature of the facility's business leader. Progress on corrective actions is monitored closely.

Instances of potential non-compliance and EMS non-conformances are corrected as soon as possible.

g. When was the last Senior Management review of your EMS completed? *mo/yr* A facility's MAP is reviewed by its management board and personally endorsed by its President at least once a year per J&J requirement.

Who headed the review?

Name: Mr./Mrs./Ms./Dr. C. Austin

Title: President

Section B

(continued)

B.2 **ISO 14001 Certification.** Is your facility currently certified to ISO 14001? ☒ Yes ☐ No

B.3 **Environmental Aspects Identification.** When did your facility last conduct a systematic identification and/or review of your environmental aspects? *mo/yr* Every facility conducts a review of its environmental aspects at least once a year as part of its annual self-assessment.

B.4 **Progress Toward Achieving Objectives and Targets.** In the table below, please provide a narrative summary of progress made toward EMS objectives and targets. **You may limit the summary to environmental aspects that are *significant* and towards which *progress* has been made during the *reporting year*.** In cases where progress relates specifically to a Performance Track performance commitment, complete the *Environmental Aspect* column, but in the *Progress* column simply refer to the performance commitment tables in Section C, i.e. "See Section C." Attach additional sheets as necessary.

Environmental Aspect	*Progress Made This Year* *(e.g., quantitative or qualitative improvements, activities conducted)*

Section C

Environmental Performance Commitments

Please use the tables on pages 6-9 to summarize your facility's environmental performance against your Performance Track performance commitments. Complete only those boxes related to the baseline, current year, and performance commitment. If any of the boxes have been pre-completed for you, please verify the information. If you find information that is incorrect, cross it out and write in the correct information. **Leave blank any columns for future reporting years.**

C.1

Performance Commitment 1

a. Use this table to report data related to your first performance commitment.

Category (see page 16 of the instructions): Materials Use					
Aspect (see page 16 of the instructions): Total Materials Use					
	Baseline *(as stated in your application)*	*Year 1*	*Year 2*	*Year 3*	*Performance Commitment* *(the goal stated in your application)*
Calendar Year	2000	2001			2003
Actual Quantity (per year)	243,942.6	301,798.2			(optional)
Measurement Units	lbs				
*Normalizing Factor**	1.0	N/A			(optional)
*Basis for your Normalizing Factor**	This facility does not have a normalizing factor immediately available. The facility will work with EPA and consider possibilities for providing this information with the 2002 annual performance report.				
*Normalized Quantity** *(per year)*	243,942.6	N/A			
*See pages 17-19 of the instructions for more information					

b. Briefly describe how you achieved improvements for this aspect or, if relevant, any circumstances that delayed progress.

c. Please list any other EPA voluntary programs to which you are also reporting these data (e.g., Energy Star, Project XL).

Section C

(continued)

C.2 Performance Commitment 2

a. Use this table to report data related to your second performance commitment.

Category (see page 16 of the instructions): Waste					
Aspect (see page 16 of the instructions): Total Solid Waste					
	Baseline *(as stated in your application)*	*Year 1*	*Year 2*	*Year 3*	*Performance Commitment* *(the goal stated in your application)*
Calendar Year	2000	2001			2003
Actual Quantity (per year)	185	250			(optional)
Measurement Units	tons				
*Normalizing Factor**	1.0	N/A			(optional)
*Basis for your Normalizing Factor**	This facility does not have a normalizing factor immediately available. The facility will work with EPA and consider possibilities for providing this information with the 2002 annual performance report.				
*Normalized Quantity** *(per year)*	185	N/A			
*See pages 17-19 of the instructions for more information					

b. Briefly describe how you achieved improvements for this aspect or, if relevant, any circumstances that delayed progress.

c. Please list any other EPA voluntary programs to which you are also reporting these data (e.g., Energy Star, Project XL).

Section C

(continued)

C.3 Performance Commitment 3

a. Use this table to report data related to your third performance commitment.

Category (see page 16 of the instructions): Air Emissions					
Aspect (see page 16 of the instructions): Emissions of Greenhouse Gases					
	Baseline *(as stated in your application)*	*Year 1*	*Year 2*	*Year 3*	*Performance Commitment* *(the goal stated in your application)*
Calendar Year	1990	2001			2003
Actual Quantity (per year)	15,559,364	39,819,881			(optional)
Measurement Units	lbs				
*Normalizing Factor**	1.0	N/A			(optional)
*Basis for your Normalizing Factor**	This facility does not have a normalizing factor immediately available. The facility will work with EPA and consider possibilities for providing this information with the 2002 annual performance report.				
*Normalized Quantity** *(per year)*	15,559,364	N/A			
*See pages 17-19 of the instructions for more information					

b. Briefly describe how you achieved improvements for this aspect or, if relevant, any circumstances that delayed progress.

c. Please list any other EPA voluntary programs to which you are also reporting these data (e.g., Energy Star, Project XL).

Section C

(continued)

C.4 Performance Commitment 4

a. Use this table to report data related to your fourth performance commitment.

Category (see page 16 of the instructions): Water Use					
Aspect (see page 16 of the instructions): Total Water Use					
	Baseline *(as stated in your application)*	*Year 1*	*Year 2*	*Year 3*	*Performance Commitment* *(the goal stated in your application)*
Calendar Year	2000	2001			2003
Actual Quantity (per year)	16,765,943.5	16,080,417			(optional)
Measurement Units	gallons				
*Normalizing Factor**	1.0	N/A			(optional)
*Basis for your Normalizing Factor**	This facility does not have a normalizing factor immediately available. The facility will work with EPA and consider possibilities for providing this information with the 2002 annual performance report.				
*Normalized Quantity** *(per year)*	16,765,943.5				
*See pages 15-17 of the instructions for more information					

b. Briefly describe how you achieved improvements for this aspect or, if relevant, any circumstances that delayed progress.

c. Please list any other EPA voluntary programs to which you are also reporting these data (e.g., Energy Star, Project XL).

Section D

Public Outreach and Performance Reporting

D.1 Please briefly summarize the public outreach and reporting activities that your facility has conducted during the year. Feel free, but not obligated, to attach supporting materials (e.g., meeting agendas, public announcements).

D.2 Please indicate which of the following methods your facility plans to use to make its Performance Track Annual Performance Report available to the public. Please check as many as are appropriate.

☐ Website (URL)

☐ Open House

☐ Meetings

☐ Press Releases

☐ Community Advisory Panel

☒ Other Johnson & Johnson published its 2001 Annual EH&S Sustainability Report in April 2002. It contains our 2001 performance results. The report is available in hard copy and on the J&J Web site, http://www.jnj.com/who_is_jnj/environment.html.

Section E

Self-Certification of Continued Program Participation

On behalf of Ortho Biologics, LLC,
(name of my facility)
I certify that

- I have read and agree to the terms and conditions specified in *the National Environmental Performance Track Program Guide*. This facility, to the best of my knowledge, continues to meet all program criteria;
- I have personally examined and am familiar with the information contained in this Annual Performance Report. The information contained in this report is, to the best of my knowledge and based on reasonable inquiry, true, accurate, and complete;
- My facility has an environmental management system (EMS), as defined in the Performance Track EMS criteria, including systems to maintain compliance with all applicable federal, state, tribal, and local environmental requirements in place at the facility, and the EMS will be maintained for the duration of the facility's participation in the program;
- My facility has conducted an objective assessment of its compliance with all applicable federal, state, tribal, and local environmental requirements; and the facility has corrected all identified instances of potential or actual noncompliance; and
- Based on the foregoing compliance assessments and subsequent corrective actions (if any were necessary), my facility is, to the best of my knowledge and based on reasonable inquiry, currently in compliance with applicable federal, state, tribal, and local environmental requirements.

I agree that EPA's decision whether to accept participants into or remove them from the National Environmental Performance Track is wholly discretionary, and I waive any right that may exist under any law to challenge EPA's acceptance or removal decision.

I am the senior manager with responsibility for the facility and am fully authorized to execute this statement on behalf of the corporation or other legal entity whose facility is part of the National Environmental Performance Track program.

Signature/Date _____

Printed Name Mr./Mrs./Ms./Dr. _____

Title _____

Phone Number/E-mail Address _____

Facility Name Ortho Biologics, LLC

Facility Street Address PO BOX 33333, Manati, PR 00674

Performance Track Identification Number A020015

Paperwork Reduction Act Notice

The public reporting and recordkeeping burden for this collection of information is estimated to average 188 hours per respondent annually. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. 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.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.