DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION

**RCRA Corrective Action**
**Environmental Indicator (EI) RCRAInfo code (CA750)**
**Migration of Contaminated Groundwater Under Control**

**Facility Name:** Novartis Pharmaceuticals Corp.
**Facility Address:** 59 Rte. 10. East Hanover, NJ
**Facility EPA ID #:** NJD002147023

**Background**
**Definition of Environmental Indicators (for the RCRA Corrective Action)**

Environmental Indicators (EI) are measures being used by the RCRA Corrective Action program to go beyond programmatic activity measures (e.g., reports received and approved, etc.) to track changes in the quality of the environment. The two EI developed to-date indicate the quality of the environment in relation to current human exposures to contamination and the migration of contaminated groundwater. An EI for non-human (ecological) receptors is intended to be developed in the future.

**Definition of "Migration of Contaminated Groundwater Under Control" EI**

A positive "Migration of Contaminated Groundwater Under Control" EI determination ("YE" status code) indicates that the migration of "contaminated" groundwater has stabilized, and that monitoring will be conducted to confirm that contaminated groundwater remains within the original "area of contaminated groundwater" (for all groundwater "contamination" subject to RCRA corrective action at or from the identified facility (i.e., site-wide)).

**Relationship of EI to Final Remedies**

While Final remedies remain the long-term objective of the RCRA Corrective Action program, the EI are near-term objectives which are currently being used as Program measures for the Government Performance and Results Act of 1993, (GPRA). The "Migration of Contaminated Groundwater Under Control" EI pertains ONLY to the physical migration (i.e., further spread) of contaminated ground water and contaminants within groundwater (e.g., non-aqueous phase liquids or NAPLs). Achieving this EI does not substitute for achieving other stabilization or final remedy requirements and expectations associated with sources of contamination and the need to restore, wherever practicable, contaminated groundwater to be suitable for its designated current and future uses.

**Duration / Applicability of EI Determinations**

EI Determinations status codes should remain in RCRAInfo (Resource Conservation and Recovery Act Information System) national database ONLY as long as they remain true (i.e., RCRAInfo status codes must be changed when the regulatory authorities become aware of contrary information).

1. Has **all** available relevant/significant information on known and reasonably suspected releases to the groundwater media, subject to RCRA Corrective Action (e.g., from Solid Waste Management Units (SWMUs), Regulated Units (RUs), and Areas of Concern (AOCs)), been **considered** in this EI determination?

_X__ If yes - check here and continue with #2 below.

_____ If no - re-evaluate existing data, or

_____ If data are not available, skip to #8 and enter"IN" (more information needed) status code.

**Facility Information:**

The Novartis Pharmaceuticals Corporation, East Hanover Facility (facility) occupies approximately 188 acres located primarily in the southeast quadrant of the intersection of New Jersey Route 10 and Ridgedale Avenue in East Hanover, New Jersey. A site location map is presented as Figure 1 of the Installation of Sentinel Monitoring Wells and Work Plan for Continued Periodic Groundwater Sampling (Paulus, Sokolowski & Sartor, Inc., April 2002). The property features a prominent topographic high point in the northwest-central area of the facility. Site topography may be seen in the Topography Map* produced in October 1995 by GEO Engineering, Inc. Parcels of the facility property are also located between Ridgedale Avenue and Black Brook/Whippany River, to the west of Ridgedale Avenue.

Novartis purchased the property in 1947 and constructed the first buildings for manufacturing operations in the early to mid-1950's. Facility operations began in the mid-1950's. Facility expansions were undertaken in the late 1950's, 1964 through 1969, during the early to mid-1980's and most recently in the early 1990's.

Prior to 1985, the facility operations included laboratory, production and warehouse operations related to the manufacture of dyes and pigments and pharmaceutical products. Since 1985, operations have been limited to the manufacturing, compounding, and packaging of pharmaceutical products. In addition, the facility conducts research and development of pharmaceutical products.

The facility generates, stores and disposes of liquid and solid wastes during its manufacturing operations. The wastes consist of organic and inorganic substances, including still bottom liquids, chlorinated solvents, caustic water solutions, waste oil and miscellaneous other solid and liquid wastes. Hazardous wastes generated by facility operations are stored in drums located at the Container Storage Area (Building 409, SWMU #10) and the current Alkaline Water Liquid aboveground storage tank (AST). All waste is disposed of at off-site facilities.

Contaminants of concern (COCs) which have been reported at concentrations above groundwater quality standards include chloroform, 1,2-dichloroethane, benzene, arsenic, chromium, cadmium, and lead. To date, there are twenty-two (22) monitoring wells, ranging from shallow to deep, spread throughout the facility that continue to be monitored.

The following 11 Solid Waste Management Units (SWMUs) and four Areas of Concern (AOCs) were identified in the November 23, 1994 Hazardous and Solid Waste Amendment (HSWA) Permit issued to the facility:

**SWMU #1, Two Clay-Lined Wastewater Equalization Lagoons:** The lagoons were associated with SWMU #9 and built in the early 1950s. They received process wastewater, neutralized acid wastewater, laboratory wastewater, and filter backwashing water until 1986. The lagoons were drained and excavated in 1986 and 1987 and closed in 1988 under the requirements of the Lagoon Closure Plan.

**SWMU #2, Inactive Skimming Tank:** The skimming tank handled neutralized acid wastewater from the 1950s to 1968. The tank did not receive any wastewater from 1968 to 1991 when it was removed. Sampling was conducted and no residual contamination was identified.

**SWMU #3, Active Skimming Tank:** The active skimming tank receives approximately 100,000 gallons of laboratory wastewater and scrubber water per day, and is operating under an NJDPES permit.

**SWMU #4, Caustic UST at Building 410:** The former 5,000-gallon underground storage tank (UST) was located on the east side of Building 410. The tank contained a solution of 50% sodium hydroxide and 50% water. The tank was installed in 1967 and removed in 1984.

**SWMU #5, Diesel Fuel Oil UST at Building 410:** The former 2,000-gallon Diesel Fuel UST was located northeast of Building 410, adjacent to the generator building. The UST contained diesel fuel oil which powered the emergency generator. The tank was installed in 1979 and removed in 1987 because it failed an integrity test.

**SWMU #6, Diesel Fuel Oil UST at Building 415B:** The former 1,000-gallon UST was located on the west side of Building 415B. The tank contained diesel fuel oil to power the emergency generators for Building 415B. The tank was installed in 1971 and removed in 1987 because it failed an integrity test. However, after sampling was conducted, a no further action determination was made.

**SWMU #7, Wastewater UST at Building 103:** The former 10,000-gallon UST was located northeast of Building 103. The tank contained wastewater from equipment washdown in buildings 103 and 101. The tank was installed in 1966 and removed in 1989. Sampling indicated no residual contamination.

**<u>SWMU #8, Former Incinerator at Building 401</u>:** The former incinerator was located south of building 401. The incinerator was used to incinerate trash. It was installed between 1949 and 1960 and removed in 1983. The incinerator was not used after 1971. Sampling was conducted and no residual contamination was identified.

**<u>SWMU #9, Inactive On-Site Treatment System</u>:** The inactive on-site treatment system was constructed in the 1950s and consisted of a settling/neutralization unit, clay-lined wastewater equalization lagoons, lagoon distribution box, rate control chamber, dosing chamber, large sand filter beds, recirculation unit, chlorine contact chamber, intermittent sand filter beds, and septic unit. All of the above units were removed between 1991 and 1994. Sampling indicated no residual contamination.

**<u>SWMU #10, Container Storage Area</u>:** The container storage area (CSA) is a RCRA regulated unit and is operating under a state operating permit.

**<u>SWMU #11, Former Alkaline Waste Liquid AST at Building 410</u>:** The former 5,000-gallon AST was located on the east side of Building 410. The tank contained a solution of 50% sodium hydroxide and 50% water. The tank was installed in 1968 and removed in 1975. The 5,000-gallon AST was replaced with an 8,000-gallon AST. The 8000-gallon AST was RCRA regulated and operated under a state operating permit. The replacement AST was removed in accordance with RCRA regulations in 1999.

**<u>AOC, Soils at MW-11</u>:** Soils surrounding MW-11 were delineated to determine the extent of TPH contamination around MW-11. Samples indicated TPH concentrations below the NJDEP residential Soil Cleanup Criteria of 10,000 mg/kg.

**<u>AOC, Chlorinated Compounds used at Buildings 402, 407, 408, 409, and 410</u>:** Information on this AOC was not provided in the available environmental reports. These compounds may have been investigated as part of the efforts to determine the source of soil and groundwater contamination.

**<u>AOC, Glacial Till</u>:** The glacial till unit was investigated through several geologic and hydrogeologic studies. It appears to be a low permeability unit that may act as a barrier to the downward migration of contamination. The unit appears to be unsaturated in absence of a local source of recharge.

**<u>AOC, Groundwater</u>:** Groundwater is contaminated with chlorinated volatile organic compounds (VOCs). There are exceedances of NJDEP standards for trichloroethylene (TCE), 1,1,1-trichloroethane (TCA), and chloroform. However, the TCE and TCA appear to be coming from upgradient sources. The flow of these contaminants onto the site is being facilitated by the pumping of the on-site production wells. Therefore, chloroform appears to be the only compound that is not originating from off-site sources. Inorganic compounds detected appear to be the result of naturally occurring sources.

The following AOCs were identified in the June 1997 Preliminary Assessment (PA) that was conducted for the facility:

**AOC 1- Methanol and Alcohol Storage Area:** Alcohols were stored in USTs behind Building 410. The alcohol, and other, USTs were removed from this area in 1998. New Jersey DEP issued a No Further Action (NFA) letter for the soils in this area on August 19, 1999, however, additional groundwater sampling was requested.

**AOC 2- 1,000 Gallon Underground Diesel Tank (A26) Abandoned in Place at Building 710 B:** Three soil samples were collected and analyzed for total petroleum hydrocarbons (TPH), with one sample analyzed for VOCs. The sampling results indicated organic compounds were detected at levels below the NJDEP Impact to Groundwater Soil Cleanup Criteria.

**AOC 3- Former 1,000 Gallon Underground Diesel Storage Tank (E27) at Building 403:** Six soil samples were collected from AOC 3. One sample contained TPH at 1,750 mg/kg which is above the NJDEP action level of 1,000 mg/kg but below the NJDEP soil cleanup limit of 10,000 mg/kg for total organic constituents.

**AOC 4- Former 1,000 Gallon Underground Diesel Storage Tank (E28) at Former Building 403A:** Four soil samples were collected and analyzed for TPH, with one sample analyzed for VOCs. The sampling results indicated organic compounds were detected at levels below the NJDEP Impact to Groundwater Soil Cleanup Criteria.

**AOC 5- Emergency Overflow Spill Containment Tanks (M-20, M-21, M-22, M-23, M-34):** Five soil samples and one duplicate sample were collected and analyzed for VOCs, pesticides/PCBs, and metals, with one sample analyzed for TPH. The sampling results indicated compounds were detected at levels below the NJDEP Impact to Groundwater Soil Cleanup Criteria and the available NJDEP Direct Contact Soil Criteria.

**AOC 6- July 1, 1992 Sewer Line Discharge:** Three soil samples were collected and analyzed for metals. One sample was analyzed for targeted semivolatile compounds (SVOCs). The sampling results indicated compounds were detected at levels below their respective NJDEP soil cleanup guidelines.

**AOC 7- July 6, 1982 Diesel Oil Spill at Former Building 403A Emergency Generator:** A geoprobe boring was installed to a depth of 11 feet. The soil was screened with a photoionization detector (PID) at one foot intervals and no VOCs were recorded with the PID. A sample from 8.0-8.5 feet was analyzed for VOCs and no contaminant concentrations were detected.

**AOC 8- December 16, 1994 Gasoline Discharge:** One soil sample and a duplicate were collected and analyzed for TPH and VOCs. The sampling results indicated organic compounds were detected at levels below the NJDEP Impact to Groundwater Soil Cleanup Criteria.

**AOC 9- January 3, 1994 Propylene Glycol Discharge to Storm Detention Basin (002):** One soil sample was collected. Propylene glycol was detected at 7.65 mg/kg. TPH and VOC results for this sample were below NJDEP Soil Cleanup Guidelines.

**AOC 10- Former Incinerator at Building 401:** Four surface soil (0.0 to 0.5 feet interval) samples were collected and analyzed for metals. The results were below the NJDEP Residential Direct Contact Soil Cleanup Criteria.

**AOC 11- Former Gasoline Pump Station for Former USTs E-17, E-18 and E-19 Near Building 402:** Unit closed in November 1992. NJDEP issued a No Further Action Letter for the unit on August 17, 1993.

Most of these AOCs were investigated through the New Jersey Industrial Site Recovery Act (ISRA) in May-June of 2000. In their September 2000 ISRA Site Investigation Report, the facility requested that the NJDEP issue a No Further Action (NFA) Letter for all 11 AOCs.

Attachment 1 to this document is the Summary of Media Impacts table. This table provides a synopsis of the SWMUs and AOCs, their impact to environmental media, and corrective actions completed.

**References:**

1. GEO Engineering, Inc., Initial Phase RCRA Facility Investigation Work Plan, March 1997
2. Paulus, Sokolowski & Sartor, Inc., Supplemental Hydrogeologic Investigation, February 1998
3. Haley & Aldrich, Inc., Initial RCRA Facility Investigation Report Volume I of III, March 1998
4. Paulus, Sokolowski & Sartor, Inc., Supplemental Hydrogeologic Investigation Report, January 29, 1999.
5. Paulus, Sokolowski & Sartor, Inc., Addendum to Supplemental Hydrogeologic Investigation Report, July 30, 1999
6. Paulus, Sokolowski & Sartor, Inc., Installation of Sentinel Monitoring Wells and Work Plan for Continued Periodic Groundwater Sampling, April 2002
* Note: It is not clear that the 1995 Topography Map cited here was associated with a particular report. It may have been provided by the facility in connection to the March 1997 Initial Phase

RFI Work Plan and related sampling visits. This map is referenced here because it provided what appeared to be the most detailed topographic information available for the site.

2. Is **groundwater** known or reasonably suspected to be "**contaminated**"[1] above appropriately protective "levels" (i.e., applicable promulgated standards, as well as other appropriate standards, guidelines, guidance, or criteria) from releases subject to RCRA Corrective Action, anywhere at, or from, the facility?

__X__ If yes - continue after identifying key contaminants, citing appropriate "levels," and referencing supporting documentation.

______ If no - skip to #8 and enter "YE" status code, after citing appropriate "levels," and referencing supporting documentation to demonstrate that groundwater is not "contaminated."

______ If unknown - skip to #8 and enter "IN" status code.

**Rationale:**

As noted in Section 1.0 of the Installation of Sentinel Monitoring Wells and Work Plan for Continued Periodic Groundwater Sampling report, the primary COCs according to USEPA/NJDEP for this facility are chloroform, benzene, 1,2-dichloroethane, sodium, and chlorides. To date, the source of chloroform found in on-site wells remains unclear but it appears to originate from the Novartis site. Soil analyses conducted at the facility do not reveal elevated levels for any of the constituents of concern found in the groundwater.

[1] "Contamination" and "contaminated" describes media containing contaminants (in any form, NAPL and/or dissolved, vapors, or solids, that are subject to RCRA) in concentrations in excess of appropriately protective risk-based "levels" (for the media, that identify risks within the acceptable risk range).

Analyses of groundwater samples for the facility date back to late 1986. Most notable in this historical record is the presence of chloroform and 1,2-dichloroethane. The highest concentration of chloroform recorded in an onsite monitoring well was 5,400D[2] parts per billion (ppb) in December of 1990. The highest recorded level of 1,2-dichloroethane content in groundwater was recorded in December 1986 when the contamination level reached 40 ppb yet levels of 1,2-dichloroethane contamination in groundwater at the site appear to have decreased since then as only 2 ppb were found in a single well as recently as November 2001. Sample results for 21 of the 22 existing wells show that as of late November/early December 2001, the following VOCs and SVOCs were found to exist in groundwater at levels above the defined criteria in at least one monitoring well: chloroform, 1,1-dichloroethylene, 1,2-dichloroethane, 1,1,1-trichloroethane, carbon tetrachloride, trichloroethylene, tetrachloroethylene, and bis(2-ethylhexyl)phthalate.

See Attachment 2 for a listing of additional VOCs and SVOCs and their respective maximum detected levels at the site. Attachment 2 provides a summary of the Groundwater Maximum Detected Concentrations and Comparison to NJDEP IIA Groundwater Quality Criteria.

## References:

1. Paulus, Sokolowski & Sartor, Inc., Installation of Sentinel Monitoring Wells and Work Plan for Continued Periodic Groundwater Sampling, April 2002
2. Haley & Aldrich, Inc., Initial RCRA Facility Investigation Report Volume I of III, March 1998

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[2]Dilution qualifier. Result was obtained after sample was diluted. Laboratories dilute samples for the following reasons:

1) to allow the concentration of the sample or compound to fall within the calibration or linear range of the instrument. When sample results are outside of the calibration or linear range of the instrument, there is no level of certainty associated with that result, as the laboratory has not been able to verify that their instrumentation is able to accurately and precisely measure that level of analyte. In many cases this data would be considered unusable or unreliable.

2) to address matrix interferences. Matrix interferences could be a result of many different variables including high concentrations of target or non-target compounds or tentatively identified compounds and specific media characteristics such as dense clay, emulsions or polymers and samples comprised of heavy oils or tars. Matrix interferences can cause abnormally low or high sample results. Diluting a sample with matrix interferences can remove or reduce the presence of these interferences allowing for results that are more indicative of the compounds or analytes present in the sample.

When a laboratory dilutes a sample, they are required to place a D qualifier next to the result that was obtained using dilution. In some cases only one analyte result was obtained using dilution. This is because only this analyte exceeded the instrument's calibration range during the first run. The laboratory then diluted the sample and reported the diluted result for that specific analyte. The original results for the remaining analytes were not diluted and therefore do not need the D qualifier. The D qualifier, notifies the data user that this result was obtained after the sample was diluted.

3. Has the **migration** of contaminated groundwater **stabilized** (such that contaminated groundwater is expected to remain within "existing area of contaminated groundwater"[3] as defined by the monitoring locations designated at the time of this determination)?

_X_ If yes - continue, after presenting or referencing the physical evidence (e.g., groundwater sampling/measurement/migration barrier data) and rationale why contaminated groundwater is expected to remain within the (horizontal or vertical) dimensions of the "existing area of groundwater contamination"[2]).

___ If no (contaminated groundwater is observed or expected to migrate beyond the designated locations defining the "existing area of groundwater contamination"[2]) - skip to #8 and enter "NO" status code, after providing an explanation.

___ If unknown - skip to #8 and enter "IN" status code.

**Rationale:**

Groundwater monitoring wells within the facility have been sampled since 1986. A statistical analysis was conducted on chloroform concentrations in monitoring wells DEP-3 and DEP-6 (i.e., Mann-Kendall Test, corrected for seasonal variation by isolating each season from the quarterly sampling data that was available). The results of the Mann-Kendall Test suggested that the concentrations of chloroform are stable in the onsite groundwater. Much of the available groundwater sampling data that is available is summarized in Table 29 of the Initial RCRA Facility Investigation Report dated March 1998. In addition to the statistical analyses that were conducted on the contaminant concentrations in monitoring wells DEP-3 and DEP-6, a review of the contaminant concentrations in the other monitoring wells at the site also suggest that the concentrations of contaminants are stable, with the exception of chloride.

Chloride concentrations in groundwater at the site appear to be increasing. The distribution of chloride in groundwater is different from the distribution of chloroform and it appears that the chloride plume originates from upgradient of the site. Industrial activity or a failed sanitary sewer force main upgradient of the Novartis site may be responsible for the elevated chloride concentrations as well as some of the other contaminants observed in groundwater in the vicinity

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[3] "existing area of contaminated groundwater" is an area (with horizontal and vertical dimensions) that has been verifiably demonstrated to contain all relevant groundwater contamination for this determination, and is defined by designated (monitoring) locations proximate to the outer perimeter of "contamination" that can and will be sampled/tested in the future to physically verify that all "contaminated" groundwater remains within this area, and that the further migration of "contaminated" groundwater is not occurring. Reasonable allowances in the proximity of the monitoring locations are permissible to incorporate formal remedy decisions (i.e., including public participation) allowing a limited area for natural attenuation.

of the site. Several chlorinated compounds have historically been detected at higher concentrations in monitoring wells upgradient of the site relative to onsite monitoring wells. Some of the chloride in the groundwater may be a breakdown product of the degradation of the chlorinated VOCs.

Five new monitoring wells were installed at the facility in September 2001. One of these new monitoring wells was installed in an upgradient location to monitor background conditions. The other four wells were installed in downgradient locations as sentinel wells to monitor the contaminant plume. The first two rounds of groundwater sampling for the sentinel wells were conducted in November 2001 and June 2002. The analytical results from these two rounds of groundwater sampling indicate that no contaminants are present in the sentinel wells at levels above the NJDEP IIA Groundwater Quality Criteria.

Several active production wells located southwest of the site appear to be influencing the migration of contaminants in the groundwater. The dog-leg shape of the chloroform plume in the southwestern portion of the site is apparently the result of pumping from these wells. As long as the production wells remain active it is likely that the chloroform plume, as well as other contaminants in the groundwater, will remain within the existing area of contaminated groundwater. If the pumping rates from the production wells are decreased in the future it will be necessary to reevaluate this determination of the stability of the groundwater contamination at the site.

The groundwater that is monitored beneath the site is located in a sand and gravel layer. The sand and gravel layer lies beneath a lower permeability glacial till that contains sand, silt, clay, and some coarser material. The glacial till unit underlies the Novartis facility and may act as a hydrogeologic buffer between the surface at the site and the groundwater within the sand and gravel unit. Hydrogeologic analysis of the glacial till suggests that it may generally be unsaturated except for localized recharge areas (i.e., beneath a retention basin). The water table in the sand and gravel aquifer appears to occur below the base of the glacial till, further supporting that the glacial till unit may be unsaturated. Soil sampling has been conducted at the waste management areas of the Novartis facility and so far, other than the chloroform plume, there have been no clear indications that groundwater quality in the sand and gravel aquifer may be immanently impacted by site operations. Groundwater monitoring should be continued in the vicinity of the site to assess potential delayed introductions of site contaminants into the groundwater due to contaminants migrating through the glacial till unit.

**References:**

1. Haley & Aldrich, Inc., Initial RCRA Facility Investigation Report Volume I of III, March 1998
2. Paulus, Sokolowski & Sartor, Inc., Amended Work Plan, Supplemental Hydrogeologic Investigation Report, Well Locations and Screen Depths, February 16, 2001

3. Paulus, Sokolowski & Sartor, Inc., Installation of Sentinel Monitoring Wells and Work Plan for Continued Periodic Groundwater Sampling, April 30, 2002.
4. Keyspan/Paulus, Sokolowski & Sartor, Inc., Periodic Groundwater Sampling June 2002 Results, August 16, 2002.

4. Does "contaminated" groundwater **discharge** into **surface water** bodies?

_____ If yes - continue after identifying potentially affected surface water bodies.

__X__ If no - skip to #7 (and enter a "YE" status code in #8, if #7 = yes) after providing an explanation and/or referencing documentation supporting that groundwater "contamination" does not enter surface water bodies.

_____ If unknown - skip to #8 and enter "IN" status code.

Currently available plume maps for the site suggest that the groundwater contamination associated with the Novartis facility is being captured by the production wells located southwest of the facility. No data are available that suggest "contamination," as defined in footnote 1 to EI Question No. 2, above, may be bypassing the production wells and approaching the surface water bodies west of the site. If the groundwater withdrawal rate from the production wells is decreased, additional investigation should be conducted to further assess the possibility that contaminants may bypass the production wells and enter surface water bodies west and southwest of the site.

The predominant surface water bodies in the vicinity of the site are Black Brook and the Whippany River. Wetlands are located west of these surface water bodies. Available groundwater elevation data suggest that Whippany River and the Black Brook do not accept groundwater from the stratified drift aquifer in the vicinity of the Novartis site. For example, the elevation of the potentiometric surface in the stratified drift aquifer in the vicinity of the site is generally less than 150 feet above mean sea level (amsl) according to the 2002 groundwater elevation data presented in Table 5 of the April 2002 Installation of Sentinel Monitoring Wells and Work Plan for Continued Periodic Groundwater Sampling. The 1995 topographic map presented by GEO Engineering, Inc. suggests that the Whippany River and Black Brook are generally above 170 feet amsl.

**References:**

1. Paulus, Sokolowski & Sartor, Inc., Amended Work Plan, Supplemental Hydrogeologic Investigation Report, Well Locations and Screen Depths, February 16, 2001
2. Paulus, Sokolowski & Sartor, Inc., Installation of Sentinel Monitoring Wells and Work Plan for Continued Periodic Groundwater Sampling, April 2002
3. Conversations with the East Hanover, NJ Department of Health (Mr. Peter Summers) and the Hanover Township, NJ Department of Health (Dr. George Van Orden) regarding the interaction

between the Whippany River and the Black Brook and the groundwater in the vicinity of the Novartis Site.

5. Is the **discharge** of "contaminated" groundwater into surface water likely to be "**insignificant**" (i.e., the maximum concentration[4] of each contaminant discharging into surface water is less than 10 times their appropriate groundwater "level," and there are no other conditions (e.g., the nature, and number, of discharging contaminants, or environmental setting), which significantly increase the potential for unacceptable impacts to surface water, sediments, or eco-systems at these concentrations)?

____ If yes - skip to #7 (and enter "YE" status code in #8 if #7 = yes), after documenting: 1) the maximum known or reasonably suspected concentration[3] of key contaminants discharged above their groundwater "level," the value of the appropriate "level(s)," and if there is evidence that the concentrations are increasing; and 2) provide a statement of professional judgement/explanation (or reference documentation) supporting that the discharge of groundwater contaminants into the surface water is not anticipated to have unacceptable impacts to the receiving surface water, sediments, or eco-system.

____ If no - (the discharge of "contaminated" groundwater into surface water is potentially significant) - continue after documenting: 1) the maximum known or reasonably suspected concentration[3] of each contaminant discharged above its groundwater "level," the value of the appropriate "level(s)," and if there is evidence that the concentrations are increasing; and 2) for any contaminants discharging into surface water in concentrations[3] greater than 100 times their appropriate groundwater "levels," the estimated total amount (mass in kg/yr) of each of these contaminants that are being discharged (loaded) into the surface water body (at the time of the determination), and identify if there is evidence that the amount of discharging contaminants is increasing.

____ If unknown - enter "IN" status code in #8.

6. Can the **discharge** of "contaminated" groundwater into surface water be shown to be "**currently acceptable**" (i.e., not cause impacts to surface water, sediments or eco-

[4] As measured in groundwater prior to entry to the groundwater-surface water/sediment interaction (e.g., hyporheic) zone.

systems that should not be allowed to continue until a final remedy decision can be made and implemented[5])?

____ If yes - continue after either: 1) identifying the Final Remedy decision incorporating these conditions, or other site-specific criteria (developed for the protection of the site's surface water, sediments, and eco-systems), and referencing supporting documentation demonstrating that these criteria are not exceeded by the discharging groundwater; OR 2) providing or referencing an interim-assessment,[6] appropriate to the potential for impact, that shows the discharge of groundwater contaminants into the surface water is (in the opinion of a trained specialists, including ecologist) adequately protective of receiving surface water, sediments, and eco-systems, until such time when a full assessment and final remedy decision can be made. Factors which should be considered in the interim-assessment (where appropriate to help identify the impact associated with discharging groundwater) include: surface water body size, flow, use/classification/habitats and contaminant loading limits, other sources of surface water/sediment contamination, surface water and sediment sample results and comparisons to available and appropriate surface water and sediment "levels," as well as any other factors, such as effects on ecological receptors (e.g., via bio-assays/benthic surveys or site-specific ecological Risk Assessments), that the overseeing regulatory agency would deem appropriate for making the EI determination.

_____ If no - (the discharge of "contaminated" groundwater can not be shown to be "**currently acceptable**") - skip to #8 and enter "NO" status code, after documenting the currently unacceptable impacts to the surface water body, sediments, and/or eco-systems.

_____ If unknown - skip to 8 and enter "IN" status code.

7. Will groundwater **monitoring** / measurement data (and surface water/sediment/ecological data, as necessary) be collected in the future to verify that contaminated groundwater has remained within the horizontal (or vertical, as necessary) dimensions of the "existing area of contaminated groundwater?"

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[5] Note, because areas of inflowing groundwater can be critical habitats (e.g., nurseries or thermal refugia) for many species, appropriate specialist (e.g., ecologist) should be included in management decisions that could eliminate these areas by significantly altering or reversing groundwater flow pathways near surface water bodies.

[6] The understanding of the impacts of contaminated groundwater discharges into surface water bodies is a rapidly developing field and reviewers are encouraged to look to the latest guidance for the appropriate methods and scale of demonstration to be reasonably certain that discharges are not causing currently unacceptable impacts to the surface waters, sediments or eco-systems.

__X__ If yes - continue after providing or citing documentation for planned activities or future sampling/measurement events. Specifically identify the well/measurement locations which will be tested in the future to verify the expectation (identified in #3) that groundwater contamination will not be migrating horizontally (or vertically, as necessary) beyond the "existing area of groundwater contamination."

_____ If no - enter "NO" status code in #8.

_____ If unknown - enter "IN" status code in #8.

Ongoing groundwater monitoring is taking place at the Novartis facility in accordance with Task IV of the November 23, 1994 HSWA Permit issued to Novartis by the U.S. EPA. The Installation of Sentinel Monitoring Wells and Work Plan for Continued Groundwater Sampling dated April 30, 2002, provides information on additional groundwater sampling that will take place through March 2004. According to the April 2002 Work Plan, the sentinel monitoring wells S101U, S101L, S102, and S103 will be sampled quarterly for TCL+30, TAL Metals, cyanide, and chlorides. The sentinel wells, select DEP and PSS wells, and the production wells P-3, P-4, P-5, and P-6 will be sampled annually for the same suite of analyses as the quarterly sampling.

**References:**

1. Paulus, Sokolowski & Sartor, Inc., Installation of Sentinel Monitoring Wells and Work Plan for Continued Periodic Groundwater Sampling, April 2002

8. Check the appropriate RCRIS status codes for the Migration of Contaminated Groundwater Under Control EI (event code CA750), and obtain Supervisor (or appropriate Manager) signature and date on the EI determination below (attach appropriate supporting documentation as well as a map of the facility).

__X__ YES - Yes, "Migration of Contaminated Groundwater Under Control" has been verified. Based on a review of the information contained in this EI determination, it has been determined that the "Migration of Contaminated Groundwater" is "Under Control" at the Novartis facility , EPA ID # NJD002147023 , located at 59 Rte. 10, East Hanover, NJ . Specifically, this determination indicates that the migration of "contaminated" groundwater is under control, and that monitoring will be conducted to confirm that contaminated groundwater remains within the "existing area of contaminated groundwater." This determination will be re-evaluated when the Agency becomes aware of significant changes at the facility.

____ NO - Unacceptable migration of contaminated groundwater is observed or expected.

___ IN - More information is needed to make a determination.

____________________________ Date: ____________________

Sameh Abdellatif,
Environmental Engineer
RCRA Programs Branch
EPA Region 2

____________________________ Date: ____________________

Barry Tornick, Section Chief
RCRA Programs Branch
EPA Region 2

Approved by: Original signed by: Date: 3/28/2003

Adolph Everett, Chief
RCRA Programs Branch
EPA Region 2

**Locations where References may be found:**

References reviewed to prepare this EI determination are identified after each response. Reference materials are available at the EPA Region 2 offices located at 290 Broadway, 22nd Floor, New York, New York.

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| **Contact Name** | Sameh Abdellatif, EPA Project Manager |
| **Telephone** | (212) 637-4103 |
| **E-mail** | abdellatif.sameh@epamail.epa.gov |

## Attachment 1 - Summary of Media Impacts Table
## Novartis Pharmaceuticals Corporation

| SWMU OR AREA OF CONCERN (AOC) | GW | AIR (Indoors) | SURF SOIL | SURF WATER | SED | SUB SURF SOIL | AIR (Outdoors) | CORRECTIVE ACTION MEASURE and STATUS | KEY CONTAMINANTS |
|---|---|---|---|---|---|---|---|---|---|
| SWMU #1, Two Clay-Lined Wastewater Equalization Lagoons | no | no | yes | no | no | yes | no | Drained and excavated in 1986 and 1987 and closed in 1988 per the Lagoon Closure Plan | Carbon disulfide, SVOCs, pesticides, PCBs, |
| SWMU #2, Inactive Skimming Tank | no | no | no | no | no | yes | no | Removed in 1991 | VOCs, SVOCs, PCBs, arsenic, mercury |
| SWMU #3, Active Skimming Tank | no | no | no | no | no | yes | no | Operating unit. Detections of compounds below NJDEP Soil Cleanup Criteria | TPH, methylene chloride, chloroform, PCE, 1,2-DCE, TCE, methanol |
| SWMU #4, Caustic UST at Building 410 | no | no | no | no | no | yes | no | Tank and some impacted soil removed in 1984. Additional investigation indicates elevated pH to depths of 20 feet. | PH |
| SWMU #5, Diesel Fuel Oil UST at Building 410 | no | no | no | no | no | yes | no | Removed in 1987 after failing an integrity test. Some TPH impacted soil (below NJDEP SCC) left in place. | TPH |
| SWMU #6, Diesel Fuel Oil UST at Building 415B | no | no | no | no | no | yes | no | Removed in 1987 after failing an integrity test. Some TPH impacted soil (below NJDEP SCC) left in place. Three 10" vent pipes installed to promote degradation. | TPH |
| SWMU #7, Wastewater UST at Building 103 | no | no | no | no | no | yes | no | UST removed in 1985. Detected compounds below NJDEP action levels. | Methylene chloride, TCE, pentachlorophenol, and arsenic |
| SWMU #8, Former Incinerator at Building 401 | – | – | – | – | – | -- | -- | Not investigated during RFI. See AOC 10, below. | -- |
| SWMU #9, Inactive On-Site Treatment System | no | no | no | no | no | yes | no | Units removed from 1991 to 1994. Beryllium is the only compound | TPH, methylene chloride, beryllium. |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | detected that exceeded NJDEP residential Soil Cleanup Criteria. | |
| SWMU #10, Container Storage Area | – | – | – | – | – | -- | -- | Permitted unit. Not investigated during the RFI. | -- |
| SWMU #11, Former Alkaline Waste Liquid AST at Building 410 | no | no | no | no | no | yes | no | AST removed in 1975. Compounds detected below NJDEP RSCC. | methylene chloride, ethylbenzene, total xylenes |
| AOC, Soils at MW-11 | no | no | no | no | no | yes | no | TPH levels below 1,000 mg/kg which is below the NJDEP SCC of 10,000 mg/Kg. | TPH |
| AOC, Chlorinated Compounds used at Buildings 402, 407, 408, 409, and 410 | – | – | – | – | – | -- | -- | This unit was not investigated in the available reports. | -- |
| AOC, Glacial Till | – | – | – | – | – | -- | -- | Investigated through site investigations. | -- |
| AOC, Groundwater | yes | no | no | no | no | no | no | Monitoring well network in place to monitor groundwater. | Chloroform, other chlorinated VOCs, chloride. |
| AOC 1- Methanol and Alcohol Storage Area | no | no | no | no | no | no | no | USTs removed. Samples were found to be below the respective cleanup guideline (soil) or standard (groundwater) | methanol, isopropyl alcohol, toluene, methyl tertiary butyl ether |
| AOC 2- 1,000 Gallon Underground Diesel Tank (A26) Abandoned in Place at Building 710 B | no | no | no | no | no | no | no | Results of soil testing at AOC 2 were below cleanup guidelines. | TPHC, VOCs |
| AOC 3- Former 1,000 Gallon Underground Diesel Storage Tank (E27) at Building 403 | no | no | no | no | no | no | no | Results of soil testing at AOC 3 were below cleanup guidelines. | TPHC, VOCs |
| AOC 4- Former 1,000 Gallon Underground Diesel Storage Tank (E28) at Former Building 403A | no | no | no | no | no | no | no | Results of soil testing at AOC 4 were below cleanup guidelines. | TPHC, VOCs |
| AOC 5- | no | no | no | no | no | no | no | Results of soil | VOC, |

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|---|---|---|---|---|---|---|---|---|---|
| Emergency Overflow Spill Containment Tanks (M-20, M-21, M-22, M-23, M-34) | | | | | | | | testing at AOC 5 were below cleanup guidelines | pesticides/PCBs, metals |
| AOC 6- July 1, 1992 Sewer Line Discharge | no | no | no | no | no | no | no | Results of soil testing at AOC 6 were below cleanup guidelines | metals, SVOCs |
| AOC 7- July 6, 1982 Diesel Oil Spill at Former Building 403A Emergency Generator | no | no | no | no | no | yes | no | In 1982, Novartis removed as much contaminated soil as possible without damaging the structural integrity of the building and pad and disposed of according to regulations. Results of soil testing at AOC 7 were below cleanup guidelines | VOCs |
| AOC 8- December 16, 1994 Gasoline Discharge | no | no | yes | no | no | yes | no | Spill area was excavated 4 to 6 inches below ground surface. Four 55-gallon drums of affected soil were removed to the RCRA hazardous waste storage shed. Results of soil testing conducted at AOC 8 were below cleanup guidelines. | TPH, VOCs |
| AOC 9- January 3, 1994 Propylene Glycol Discharge to Storm Detention Basin (002) | no | no | yes | no | no | yes | no | 5,000 gallons of water was vacuum extracted and disposed of in accordance with applicable regulations. | Alcohols, VOCs, methanol, ethanol, propylene glycol |
| AOC 10- Former Incinerator at Building 401 | no | no | no | no | no | no | no | Results of soil testing at AOC 10 were below cleanup guidelines | metals |
| AOC 11- Former Gasoline Pump Station for Former USTs Near Bldg. 402 | no | no | no | no | no | no | no | Unit closed in November 1992. NFA letter issued by NJDEP 8/17/93. | TPHs |