



US Army Corps  
Of Engineers  
Wilmington District

# PUBLIC NOTICE

Issue Date: July 22, 2021  
Comment Deadline: August 20, 2021  
Corps Action ID Number: SAW-2021-01565

The Wilmington District, Corps of Engineers (Corps) received an application from Fujifilm Diosynth Biotechnologies U.S.A., Inc. seeking Department of the Army (DA) authorization to discharge fill material into waters and wetlands in the Cape Fear River Basin, Hydrologic Unit Code (HUC) 03030004, associated with Project Galaxy, in Holly Springs, in Wake County, North Carolina.

Specific plans and location information are described below and shown on the attached plans. This Public Notice and all attached plans are also available on the Wilmington District Web Site at:

<https://www.saw.usace.army.mil/Missions/Regulatory-Permit-Program/Public-Notices/>

**Applicant:** Fujifilm Diosynth Biotechnologies U.S.A., Inc.  
Attn: Thomas Schmalzbauer  
101 J Morris Commons Lane  
Morrisville, North Carolina 27560

**AGENT (if applicable):** Timmons Group  
Attn: Matt J. Michel  
428 Eastwood Road  
Wilmington, North Carolina 28403

## Authority

The Corps evaluates this application and decides whether to issue, conditionally issue, or deny the proposed work pursuant to applicable procedures of the following Statutory Authorities:

- Section 404 of the Clean Water Act (33 U.S.C. 1344)
- Section 10 of the Rivers and Harbors Act of 1899 (33 U.S.C. 403)
- Section 103 of the Marine Protection, Research and Sanctuaries Act of 1972 (33 U.S.C. 1413)

## Location



fill-finish and assembly, packaging, and labeling services. A warehouse building would provide storage of raw materials and finished drug products and serve as the facility's distribution hub. The facility would also consist of Quality Control (QC) Laboratory and Administration Buildings where drug samples would be managed, and QC tested. Construction of the facility would proceed under four phases, with Phases 1 and 2 being concentrated at the eastern portion of the Site and Phases 3 and 4 concentrated at the western portion.

Once completed, the facility would become the largest end-to-end cell culture biopharmaceutical contract development and manufacturing organization (CDMO) facility in North America. As a CDMO, FDBU's focus is to combine technical leadership in cell culture, microbial fermentations and gene therapies with world class Good Manufacturing Practices (GMP) facilities to advance tomorrow's medicine. For over 30 years, FDBU's focus has been on supporting their customers with the development and manufacture of recombinant proteins, viral vaccines, and gene therapies. FDBU's commitment to GMP ensures that finished drug products are of the highest quality and are safe for human consumption and use.

The need for expanded domestic production of drug products and other biopharmaceuticals has become evident in recent years due to increased international instability, the heightened risk of global pandemics, and significant commerce disruptions. In 2019, it was estimated that only 28% of active pharmaceutical ingredients (API) are produced domestically, and this percentage has dropped in the subsequent years. The increased reliance of the United States on outsourced drug products and ingredients potentially represents a security risk and a public health hazard that can be addressed with increased domestic production. Demand for a secure domestic drug-supply chain would only increase in the future as the nation's median age increases and average life expectancies continue to rise.

Additionally, Wake County and the Town of Holly Springs has a need for jobs to support its growing population. Among all U.S. counties with greater than 1 million residents, Wake County experienced the third-highest growth rate from 2010 to 2019. The county is growing twice as fast as the rest of the state and has an estimated labor force of over 590,000 as of April 2021. Unemployment rates in Wake County have slightly rebounded from pre-COVID-19 levels but remain high for low-wage workers. This proposed project is expected to create 700 full-time new jobs and an additional number of part-time construction and contracting jobs.

Due to the anticipated need to expand domestic drug production capabilities and the projected population growth in Wake County, the need exists to develop a biopharmaceutical manufacturing and distribution facility in Holly Springs, NC. The Applicant intends to develop the Site quickly in order to meet the growing demands for pharmaceuticals in the U.S. and hopes that the facility would become operational by Spring 2025.

## Project Description

The proposed site layout for Project Galaxy meets the minimum requirements for the biopharmaceutical manufacturing facility and campus and was determined to be the most practicable long-term solution to address the Applicant's purpose and need. To accomplish the goals of the project, impacts to potential jurisdictional Waters of the U.S. are unavoidable. The development of the Site would require permanent impacts to 57,278 sq. ft. (1.31 acres) of PFO wetlands, 986 sq. ft. (0.02 acre) of POW wetlands, 179 linear feet and 1,114 sq. ft. (0.03 acre) of perennial stream channel, and 3,134 linear feet and 6,643 sq. ft. (0.15 acre) of intermittent stream channel. No temporary impacts are proposed. The permanent impacts to wetlands and streams are associated with grading, cut, and fill activities required for the construction of the proposed buildings, parking areas, access roads, and utility infrastructure development. The total impacts for the proposed Project are described in the table below.

Impact ID	Impact Description	Impact Type	Wetland Area (sq. ft.)		Stream Length (LF) and Area (sq. ft.)			
			PFO	POW	Perennial		Intermittent	
					Length	Area	Length	Area
1	Fill/Grading	Permanent	39,803	--	--	--	--	--
2	Fill/Grading	Permanent	2,637	--	--	--	--	--
3	Fill/Grading	Permanent	9,607	--	--	--	--	--
4	Fill/Grading	Permanent	--	--	--	--	1,714	3,597
5	Fill/Grading	Permanent	--	986	--	--	--	--
6	Fill/Grading	Permanent	1,172	--	--	--	--	--
7	Fill/Grading	Permanent	4,060	--	--	--	--	--
8	Fill/Grading	Permanent	--	--	--	--	994	2,295
9	Culvert	Permanent	--	--	179	1,114	--	--
10	Fill/Grading	Permanent	--	--	--	--	426	752
		<b>TOTALS:</b>	<b>57,278</b>	<b>986</b>	<b>179</b>	<b>1,114</b>	<b>3,134</b>	<b>6,643</b>
		<b>ACRES:</b>	<b>1.31</b>	<b>0.02</b>	<b>--</b>	<b>0.03</b>	<b>--</b>	<b>0.15</b>

Storm runoff from the proposed facility would be managed, treated, and ultimately directed into off-site waters. Therefore, the drainage area of the receiving waters located off-site would not be significantly reduced. The project would meet all relative requirements of Best Management Practices and Engineered Stormwater Control Measures as outlined through State and Local Stormwater rules. Stormwater management on-site would be managed and treated before discharging into down-gradient waters to protect receiving waters from degradation.

## Avoidance and Minimization

The applicant provided the following information in support of efforts to avoid and/or minimize impacts to the aquatic environment:

Impacts to jurisdictional features were avoided and minimized to the maximum extent practicable by incorporating resourceful site selection and site planning, including the use of multiple preliminary jurisdictional determinations to ensure all jurisdictional features within the Site were accurately mapped. After the wetlands were delineated, an engineering plan was developed to meet all needs at the proposed facility, while minimizing impacts to Waters of the U.S. The Applicant contends that the proposed location results in the least impacts to Waters of the U.S. while realizing the purpose and need of the project.

The applicant contends that the proposed Project has minimized the possibility of secondary impacts through implementation of planning practices that would reduce impacts on downstream water quality. Efforts to reduce secondary impacts generally include:

- Innovative site planning and use of confirmed wetland delineation
- Minimization of partial wetland/stream impacts
- Minimization of impacts to primary drainage ways and floodplains
- Strict adherence to all state and local stormwater and sediment control measures

In order to avoid secondary impacts, an Erosion and Sediment Control Plan that meets the latest State and local regulations and adheres to the methodology described in the North Carolina Sedimentation and Pollution Control Act of 1973 would be prepared. All erosion and sediment control measures would be checked for stability and operation following every runoff producing rainfall (typically, > 1 inch), but in no case less than once every week. Any necessary repairs would be made immediately to maintain all measures designed. The project would meet all relative requirements of Best Management Practices and Engineered Stormwater Control Measures as outlined through State and Local Stormwater rules.

### **Compensatory Mitigation**

The applicant offered the following compensatory mitigation plan to offset unavoidable functional loss to the aquatic environment:

Compensatory mitigation for unavoidable impacts would be achieved through the purchase of off-site mitigation credits from Wetland Mitigation Banks. If credits are unavailable at the time of permitting, compensatory mitigation would be achieved through payment into the North Carolina Division of Mitigation Services (NCDMS) in-lieu fee mitigation program.

It is anticipated that North Carolina Stream Assessment Method (NCSAM) and North Carolina Wetland Assessment Method (NCWAM) reviews would be conducted in order to assess feature quality and determine if a lower mitigation ratio is feasible. If features are determined to be high quality, it is understood that a 2:1 ratio would be required for wetland and stream mitigation credits. If a 2:1 ratio is required, impacts resulting from

the proposed project would require 2.62 wetland mitigation credits and 6,626 stream mitigation credits as detailed in the table below.

Impact ID	Impact Type	Wetland (sq. ft.) and Stream (Lf) impacts			
		PEM Wetlands	POW Wetlands	R3 Streams	R4 Streams
1	Permanent	39,803	--	--	--
2	Permanent	2,637	--	--	--
3	Permanent	9,607	--	--	--
4	Permanent	--	--	--	1,714
5	Permanent	--	986	--	--
6	Permanent	1,172	--	--	--
7	Permanent	4,060	--	--	--
8	Permanent	--	--	--	994
9	Permanent	--	--	179	--
10	Permanent	--	--	--	426
<b>Totals:</b>		<b>57,278</b>	<b>986</b>	<b>179</b>	<b>3,134</b>
<b>Acres:</b>		<b>1.31</b>	<b>0.02</b>	<b>--</b>	<b>--</b>
<b>Mitigation Ratio:</b>		<b>2:1</b>	<b>N/A</b>	<b>2:1</b>	<b>2:1</b>
<b>Credits Required:</b>		<b>2.62</b>	<b>0</b>	<b>358</b>	<b>6268</b>

### Essential Fish Habitat

The Corps' determination is that the proposed project would not effect EFH or associated fisheries managed by the South Atlantic or Mid Atlantic Fishery Management Councils or the National Marine Fisheries Service.

### Cultural Resources

Pursuant to Section 106 of the National Historic Preservation Act of 1966, Appendix C of 33 CFR Part 325, and the 2005 Revised Interim Guidance for Implementing Appendix C, the District Engineer consulted district files and records and the latest published version of the National Register of Historic Places and initially determines that:

- Should historic properties, or properties eligible for inclusion in the National Register, be present within the Corps' permit area; the proposed activity requiring the DA permit (the undertaking) is a type of activity that will have no potential to cause an effect to an historic properties.
- No historic properties, nor properties eligible for inclusion in the National Register, are present within the Corps' permit area; therefore, there will be no historic properties affected. The Corps subsequently requests concurrence from the SHPO (or THPO).

- Properties ineligible for inclusion in the National Register are present within the Corps' permit area; there will be no historic properties affected by the proposed work. The Corps subsequently requests concurrence from the SHPO (or THPO).
- Historic properties, or properties eligible for inclusion in the National Register, are present within the Corps' permit area; however, the undertaking will have no adverse effect on these historic properties. The Corps subsequently requests concurrence from the SHPO (or THPO).
- Historic properties, or properties eligible for inclusion in the National Register, are present within the Corps' permit area; moreover, the undertaking may have an adverse effect on these historic properties. The Corps subsequently initiates consultation with the SHPO (or THPO).
- The proposed work takes place in an area known to have the potential for the presence of prehistoric and historic cultural resources; however, the area has not been formally surveyed for the presence of cultural resources. No sites eligible for inclusion in the National Register of Historic Places are known to be present in the vicinity of the proposed work. Additional work may be necessary to identify and assess any historic or prehistoric resources that may be present.

The District Engineer's final eligibility and effect determination will be based upon coordination with the SHPO and/or THPO, as appropriate and required, and with full consideration given to the proposed undertaking's potential direct and indirect effects on historic properties within the Corps-identified permit area.

### **Endangered Species**

Pursuant to the Endangered Species Act of 1973, the Corps reviewed the project area, examined all information provided by the applicant and consulted the latest North Carolina Natural Heritage Database. Based on available information:

- The Corps determines that the proposed project would not affect federally listed endangered or threatened species or their formally designated critical habitat.
- The Corps determines that the proposed project may affect federally listed endangered or threatened species or their formally designated critical habitat.
  - By copy of this public notice, the Corps initiates consultation under Section 7 of the ESA and will not make a permit decision until the consultation process is complete.
  - The Corps will consult under Section 7 of the ESA and will not make a permit decision until the consultation process is complete.

- The Corps has initiated consultation under Section 7 of the ESA and will not make a permit decision until the consultation process is complete.
- The Corps determines that the proposed project may affect federally listed endangered or threatened species or their formally designated critical habitat. Consultation has been completed for this type of activity and the effects of the proposed activity have been evaluated and/or authorized by the National Marine Fisheries Service (NMFS) in the South Atlantic Regional Biological Opinion or its associated documents, including 7(a)(2) & 7(d) analyses and Critical Habitat assessments. A copy of this public notice will be sent to the NMFS.
- The Corps is not aware of the presence of species listed as threatened or endangered or their critical habitat formally designated pursuant to the Endangered Species Act of 1973 (ESA) within the project area. The Corps will make a final determination on the effects of the proposed project upon additional review of the project and completion of any necessary biological assessment and/or consultation with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service.

#### **Other Required Authorizations**

The Corps forwards this notice and all applicable application materials to the appropriate State agencies for review.

**North Carolina Division of Water Resources (NCDWR):** The Corps will generally not make a final permit decision until the NCDWR issues, denies, or waives the state Certification as required by Section 401 of the Clean Water Act (PL 92-500). The receipt of the application and this public notice, combined with the appropriate application fee, at the NCDWR Central Office in Raleigh constitutes initial receipt of an application for a 401 Certification. Unless NCDWR is granted a time review extension, a waiver will be deemed to occur if the NCDWR fails to act on this request for certification within sixty days of receipt of a complete application. Additional information regarding the 401 Certification may be reviewed at the NCDWR Central Office, 401 and Buffer Permitting Unit, 512 North Salisbury Street, Raleigh, North Carolina 27604-2260. All persons desiring to make comments regarding the application for a 401 Certification should do so, in writing, by August 12, 2021 to:

NCDWR Central Office  
Attention: Mr. Rick Trone, 401 and Buffer Permitting Unit  
(USPS mailing address): 1617 Mail Service Center, Raleigh, NC 27699-1617

Or,

(physical address): 512 North Salisbury Street, Raleigh, North Carolina 27604



**North Carolina Division of Coastal Management (NCDCM):**

- The application did not include a certification that the proposed work complies with and would be conducted in a manner that is consistent with the approved North Carolina Coastal Zone Management Program. Pursuant to 33 CFR 325.2 (b)(2) the Corps cannot issue a Department of Army (DA) permit for the proposed work until the applicant submits such a certification to the Corps and the NCDCM, and the NCDCM notifies the Corps that it concurs with the applicant's consistency certification. As the application did not include the consistency certification, the Corps will request, upon receipt,, concurrence or objection from the NCDCM.
  
- Based upon all available information, the Corps determines that this application for a Department of Army (DA) permit does not involve an activity which would affect the coastal zone, which is defined by the Coastal Zone Management (CZM) Act (16 U.S.C. § 1453).

**Evaluation**

The decision whether to issue a permit will be based on an evaluation of the probable impacts including cumulative impacts of the proposed activity on the public interest. That decision will reflect the national concern for both protection and utilization of important resources. The benefit which reasonably may be expected to accrue from the proposal must be balanced against its reasonably foreseeable detriments. All factors which may be relevant to the proposal will be considered including the cumulative effects thereof; among those are conservation, economics, aesthetics, general environmental concerns, wetlands, historic properties, fish and wildlife values, flood hazards, flood plain values (in accordance with Executive Order 11988), land use, navigation, shoreline erosion and accretion, recreation, water supply and conservation, water quality, energy needs, safety, food and fiber production, mineral needs, considerations of property ownership, and, in general, the needs and welfare of the people. For activities involving the discharge of dredged or fill materials in waters of the United States, the evaluation of the impact of the activity on the public interest will include application of the Environmental Protection Agency's 404(b)(1) guidelines.

**Commenting Information**

The Corps of Engineers is soliciting comments from the public; Federal, State and local agencies and officials, including any consolidated State Viewpoint or written position of the Governor; Indian Tribes and other interested parties in order to consider and evaluate the impacts of this proposed activity. Any comments received will be considered by the Corps of Engineers to determine whether to issue, modify, condition or deny a permit for this proposal. To make this decision, comments are used to assess impacts on endangered species, historic properties, water quality, general environmental effects and the other public interest factors listed above. Comments are used in the preparation of an Environmental Assessment (EA) and/or an Environmental Impact Statement (EIS)

pursuant to the National Environmental Policy Act (NEPA). Comments are also used to determine the need for a public hearing and to determine the overall public interest of the proposed activity.

Any person may request, in writing, within the comment period specified in this notice, that a public hearing be held to consider the application. Requests for public hearings shall state, with particularity, the reasons for holding a public hearing. Requests for a public hearing will be granted, unless the District Engineer determines that the issues raised are insubstantial or there is otherwise no valid interest to be served by a hearing.

The Corps of Engineers, Wilmington District will receive written comments pertinent to the proposed work, as outlined above, until 5pm, August 20, 2021. Comments should be submitted to Mr. George Lyle Phillips III, Raleigh Regulatory Field Office, 3331 Heritage Trade Drive, Suite 105 , Wake Forest, North Carolina 27587, at (919) 554-4884-ext 25 or via email at [George.L.Phillips@usace.army.mil](mailto:George.L.Phillips@usace.army.mil).